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OSE Integrated Review

Date:	July 5, 2018
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Product Name:	Nuplazid (pimavanserin)
Subject:	Death and Other Adverse Events of Interest

Application Type/Number: NDA 207318

Applicant/Sponsor: Acadia

OSE RCM #: 2018-607

TSI #: 1890

**** This document contains drug utilization data provided by the Sponsor that are confidential and for internal FDA purposes only; this information cannot be released or discussed publicly without the Sponsor's approval.****

Special thanks to Dr. Daniel Woronow for his assistance with this review.

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EXECUTIVE SUMMARY

The Division of Psychiatry Products (DPP) consulted the Division of Pharmacovigilance (DPV) to evaluate the FDA Adverse Event Reporting System (FAERS) reports of pimavanserin since approval due to the large number of death reports in Acadia's (the Sponsor) periodic adverse event report, and also highlighted in the Institute for Safe Medication Practices QuarterWatch Report. Additionally, a FAERS data mining analysis by the Division of Applied Regulatory Science suggested risks of autonomic dysfunction, falls and insomnia with pimavanserin. DPP opened a Tracked Safety Issue to address these concerns. This review evaluates the safety profile of pimavanserin using a surveillance summary approach.

Our review did not identify any new safety findings with pimavanserin, compared to the premarketing safety profile. A large proportion (85%) of reports of fatalities and serious adverse events (SAEs) were collected through solicited reporting via a patient support program and specialty pharmacy network, in which the company actively contacts patients and families and inquires about adverse events. Most solicited cases provided insufficient information to assess drug-event causality. Because of limited clinical details and the presence of several underlying patient risk factors, these postmarketing AE reports are challenging to interpret. The controlled trials in Parkinson's disease psychosis (PDP) demonstrated increased rates of all-cause mortality and all-cause SAEs in the pimavanserin group compared to the placebo group. However, there were no unifying adverse events or mechanisms to explain these findings. Several factors contribute to the number and types of postmarketing reports of fatalities and other SAEs with pimavanserin. PD patients in general have a high mortality rate, and PDP is considered an end-stage condition, particularly when associated with dementia and long-term care settings.

In addition, many PDP patients in postmarketing reports were treated concomitantly with other antipsychotics, which further increases the risk of all-cause mortality in PD patients and elderly patients with dementia-related psychosis. Many antipsychotics including pimavanserin can also prolong the QT interval. It is possible that pimavanserin contributed to some of the postmarketing fatal and other SAEs, possibly through QT prolongation or other currently unidentified mechanisms.

Pimavanserin is almost exclusively distributed by specialty pharmacies and specialty distributors. Frequent contact with consumers via reimbursement hubs, patient assistance programs, or specialty pharmacies can explain the high number of postmarketing AE reports for pimavanserin. Drug utilization data and FAERS data showed patients aged 70 years or older accounted for the highest proportion of pimavanserin use.

We recommend revising the Warnings and Precautions and Drug Interactions sections of labeling to emphasize the risks of QT prolongation and serious cardiovascular events, particularly during concomitant use of pimavanserin and other drugs known to cause QT prolongation. We recommend listing specific antipsychotics and antidepressants known to cause QT interval prolongation, which are used commonly in PDP patients. We recommend considering issuing a Drug Safety Communication regarding these risks.

1. INTRODUCTION

The Division of Psychiatry Products (DPP) consulted the Division of Pharmacovigilance (DPV) to evaluate the FDA Adverse Event Reporting System (FAERS) reports of pimavanserin since approval due to the large number of death reports in Acadia's (the Sponsor) periodic adverse event report (PADER), and also highlighted in the Institute for Safe Medication Practices (ISMP) QuarterWatch Report. Additionally, a FAERS data mining analysis by the Division of Applied Regulatory Science (DARS) suggested risks of autonomic dysfunction, falls and insomnia with pimavanserin. DPP opened a Tracked Safety Issue (TSI) to address these concerns. This review evaluates the safety profile of pimavanserin using a surveillance summary approach.

To inform potential regulatory action, DPV and the Divisions of Epidemiology (DEPI) I and II analyzed the following:

- FAERS data
- Clinical safety findings from the new drug application (NDA) review
- DARS review
- Thorough QT (TQT) study results
- Sponsor's PADER
- Sponsor's responses to the FDA's information requests (IR) for
    - additional information on and analysis of the postmarketing adverse event (AE) reports, especially the AEs involving or leading to death
    - clarification on the mortality rate calculation
    - drug utilization data
- Relevant published medical literature on Parkinson's disease (PD), Parkinson's disease psychosis (PDP), and the use of antipsychotics in PD and dementia

1.1. BACKGROUND

Media Attention

The ISMP publishes the QuarterWatch Reports to provide their perspective on emerging drug risks using the publicly available FAERS reports as their primary source of data. On November 1, 2017, the ISMP published the QuarterWatch Report – Safety Signals for Two Novel Drugs,[1] which focused on early AE data for pimavanserin. The Report shared concerns for the high volumes of AEs of "Hallucination," "Confusional state," "Drug ineffective," and "Death." ISMP stated that pimavanserin was approved on limited scientific evidence of its benefits. It also noted a safety concern of concomitant use with antipsychotics, which are not recommended for use in the elderly (see antipsychotics class Boxed Warning in **Section 1.3**), and are not approved for use in patients with PD. Furthermore, ISMP noted that this subset of patients were each taking a median of 10 different drugs.

On April 9, 2018, the Cable News Network (CNN) published an article titled "FDA worried drug was risky; now reports of deaths spark concern."[2] This article reported stories and interviews from caregivers, physicians, medical researchers and other experts. In addition, the article summarized ISMP's QuarterWatch Report, and responses from the Sponsor and FDA.

Parkinson's disease (PD) and Parkinson's disease psychosis (PDP)

PD is a progressive neurodegenerative disease that begins between 45 and 70 years of age, with the peak age of onset in the 60s. PD affects approximately 1 million people in North America.[3,4] Core features of PD include hypokinesia, bradykinesia, resting tremor, postural instability, and rigidity.[3] Progression of PD is characterized by worsening of motor features, and advanced stage disease is also associated with treatment-resistant motor features including gait and balance problems, and dysphagia.[5,6]

The mortality rate in PD is greater than that of many common life-threatening diseases in the elderly. In a large retrospective cohort study of Medicare patients, 64% of patients with PD died during the 6-year study period.[7] Dementia was the strongest risk factor for mortality in patients with PD.[7] The mortality rate for patients with incident PD was comparable to those for incident diagnoses of acute myocardial infarction (MI), hip fracture, and Alzheimer's disease. The PD adjusted mortality rate was higher than in patients with incident colorectal cancer, cerebrovascular accident (CVA), ischemic heart disease, and chronic obstructive pulmonary disease (COPD). The most common reasons for hospitalization in patients with terminal PD were infection, cardiovascular disease, and noninfectious pulmonary disease. Another retrospective cohort study using an administrative database demonstrated that patients with PD had a 43% greater risk of all-cause mortality compared to the general population of patients over the age of 65 years.[8] The most common causes of death for patients with PD were cardiovascular, neurologic, and respiratory disorders.

As the disease advances, psychosis can occur in 30 to 60% of drug-treated patients with PD.[6,9,10] PDP is a serious, highly disabling, late complication of treated PD, usually occurring 10 or more years after the initial diagnosis of PD.[11] The onset of PDP typically signals a malignant disease course and poor prognosis.[12] Risk factors associated with the onset of psychosis in PD include dementia, older age, longer duration of PD disease, more severe motor, axial and visual impairment, depression, and sleep disturbance.[11] PDP is mainly characterized by the presence of visual hallucinations, often in the form of people (known or unknown), animals[13], insects, or inanimate objects; however, hallucinations can also involve auditory, tactile, gustatory, or cenesthetic (involving viscera) phenemona.[14] Psychosis causes severe distress to patients, families, and caregivers. Delusions in particular, often the most serious symptoms of PDP, can lead to dangerous, disorganized, and suicidal behavior.[9] Hallucinations and delusions are frequently the reasons for nursing home placement, more commonly than either dementia or severe motor impairment.[9]

In addition, PDP is associated with increased mortality especially in patients with dementia and nursing home placement.[15] The reported mean survival times for patients with PDP vary among studies published in the literature; the range appears to be 2 to 4 years after recognition of psychosis.[15] In one study of patients with PDP requiring antipsychotic treatment, 30% died during the 4-month study period.[16] The most common causes of death were pneumonia and other pulmonary disorders.[16] In another long-term study of patients with PDP, 25% were deceased at 2 years, 42% were in nursing homes, and 68% had a diagnosis of dementia.[14] The most common cause of death in the study was pneumonia, followed by urosepsis, stroke, MI, and COPD. A

long-term observational study in patients with PD demonstrated that the presence of dementia increased the mortality risk more than 2-fold.[17]

Treatment options for PDP included dose reduction of antiparkinson/dopaminergic therapy (if contributing to PDP) or addition of antipsychotics such as quetiapine or clozapine (serotonergic and dopaminergic antagonist).[18] These treatments may improve PDP symptoms, however, they can worsen motor symptoms. In addition, these antipsychotics are not FDA-approved for PDP. As discussed in the antipsychotic medication class boxed warning, controlled trials demonstrated that antipsychotics increase the risk of mortality in elderly patient with dementia-related psychosis and behavioral disturbances. In addition, there appears to be an association between antipsychotic use and mortality risk in patients with PD, as demonstrated by a retrospective matched-cohort study.[19] Antipsychotic use was associated with a greater than 2-fold hazard ratio of death compared with nonuse. The authors note that patients with PD have disease-related morbidities that may predispose them to or overlap with common antipsychotic-related adverse events (AEs), including falls, orthostatic hypotension, parkinsonism, and sedation.[19]

Pimavanserin was the first atypical antipsychotic drug approved by FDA for the treatment of hallucinations and delusions associated with PDP in April 2016. Pimavanserin acts as a selective serotonin 5-HT_{2A} receptor inverse agonist and antagonist. Unlike other atypical antipsychotics, pimavanserin does not have activity at dopaminergic receptors, including D_2.[20] Pimavanserin is approved in the U.S. only.

1.2. REGULATORY HISTORY

FDA approved pimavanserin for the treatment of hallucinations and delusions associated with PDP under the NDA 207318 on April 29, 2016. Pimavanserin is available as 17 mg oral tablets, and the recommended dosage is 34 mg once daily without titration. Pimavanserin is the only drug product indicated for the treatment of PDP. Drugs used off-label for the treatment of PDP include clozapine, quetiapine, and other antipsychotics.

1.2.1 Clinical Safety Findings from the NDA Review[21]

The approval of pimavanserin was based on a single placebo-controlled trial demonstrating efficacy in subjects with PDP. Accompanying data included results from three placebo-controlled pimavanserin trials that did not demonstrate efficacy, as well as two uncontrolled, long-term extension studies of pimavanserin in patients with PDP. In the clinical program, 616 patients with PDP had been exposed to pimavanserin at the time of data lock for the original NDA submission. Paul Andreason, M.D., Clinical Reviewer in DPP performed the NDA clinical review.

Common AEs in the Pimavanserin Trials

In the placebo-controlled trials, the most common AEs (occurring more frequently in the pimavanserin group compared to the placebo group) were peripheral edema (7% vs. 2%), confusional state (6% vs. 3%), hallucinations (5% vs. 3%), gait disturbance (2% vs. < 1%), nausea (7% vs. 4%), and constipation (4% vs. 3%). The types of hallucinations included visual, auditory, tactile, and somatic. A higher proportion of subjects in the pimavanserin group discontinued from the study because of AEs, compared with the placebo group (8% vs. 4%).

The AEs associated with discontinuation that were more common in the pimavanserin group were hallucination (2% vs. < 1%), urinary tract infection (1% vs. < 1%), and fatigue (1% vs. 0).

Deaths and Serious Adverse Events (SAEs) in the Pimavanserin Studies

In the 6-week, placebo-controlled trial population of the pimavanserin clinical program, there was an increased risk of SAEs, including death, in the pimavanserin group, compared to the placebo group. SAEs occurred in 7.9% of the pimavanserin group and 3.5% of the placebo group. In the NDA clinical review, Dr. Andreason concluded that the observed risk for SAEs in the pimavanserin 34 mg group (compared to the placebo group) was 2.38 (95% CI 1.00 to 5.73, p= 0.05).[21] For the lower dose pimavanserin (< 34 mg) group, the apparent elevated odds ratio for SAEs compared to placebo was not statistically significant [1.44 (95% CI 0.54 to 3.81, p=0.46)]. Dr. Andreason noted that there was no individual type of SAE that predominated. There appeared to be no unifying pathological mechanism or premonitory signal. Only three of 16 SAEs were viewed as "possibly drug-related" during the trials; these were psychiatric AEs. The remaining 13 of 16 SAEs were deaths and serious medical events, which were considered unrelated or unlikely to pimavanserin. Deaths occurred in four of 383 (1%) subjects in the pimavanserin group and one of 231 (0.4%) of the placebo group during the controlled trials. During the placebo-controlled trials, the causes of death in the pimavanserin group were: sepsis (n=1), septic shock (n=1), probable MI (n=1), and respiratory distress (n=1); the cause of death in the placebo group was respiratory arrest (n=1).

In the long-term PDP open-label studies with a wide duration of exposure (up to 8 years), there were 51 deaths (11.1%) among 459 subjects with PDP. The most common causes of death in the long-term open-label studies were: MI, aspiration pneumonia, pneumonia cardiac arrest, acute coronary syndrome, cardiorespiratory arrest, heart failure, sepsis, urosepsis, acute respiratory failure, CVA, and neoplasm. Dr. Andreason concluded that the types of deaths that occurred in the pimavanserin program did not appear to be pathologically uniquely different compared to what one might expect with the disease course of patients with PDP, a condition consistently associated with increased mortality.

QT Prolongation and Thorough QT (TQT) Study Results

Treatment with pimavanserin can cause significant QT prolongation. The Sponsor demonstrated a QT prolongation effect in a dedicated, moxifloxacin-controlled and placebo-controlled dedicated TQT study. As discussed in **Section 1.3**, the pimavanserin labeling includes a warning for QT prolongation. The design and results of the TQT study are discussed in more detail in **Section 3.3.2**.

1.2.2 DARS Consult Review[22]

DPV consulted DARS as part of a pilot project for identifying potential signals or risks based on data from new molecular entity NDAs. DPV and DARS selected pimavanserin for a predictive safety analysis, because it is a novel molecule for a new clinical indication. Keith Burkhart, M.D. performed the consult review.[22] The DARS team utilized several data sources including: a data mining bioinformatics tool (EFFECT), spontaneous reports from the FAERS database (and disproportionality analysis), and mechanistic data regarding a drug comparator. The purpose of

the analysis was to identify potential postmarketing events for further evaluation. Pimavanserin is a serotonin 5-HT_{2A} and 5-HT_{2C} inverse agonist. Unlike most antipsychotic drugs, pimavanserin does not demonstrate activity on dopamine D_2 receptors. The analysis used cyproheptadine as the best comparator drug, based on cyproheptadine's and pimavanserin's known target and binding profiles.

The DARS team concluded that treatment with pimavanserin has the potential to aggravate autonomic dysfunction (primarily blood pressure [BP] lability), falls, and insomnia in some patients with PDP. They noted that patients with PD are known to have these comorbidities secondary to their underlying disease process. In the EFFECT tool, cyproheptadine has a signal for hypertension. Labeling for cyproheptadine discusses hypotension. In addition, for pimavanserin, there were 12 FAERS reports noting hypertension and 19 FAERS reports of hypotension. Dr. Burkhart noted that serotonin regulation of BP is complex, "including bradycardia, tachycardia, hypotension, hypertension, and vasodilation or vasoconstriction." In animal models, there is a triphasic response to serotonin infusion, in which a transient depressor phase is followed by a pressor phase, subsequently followed by a prolonged hypotensive phase. Dr. Burkhart stated that in a patient population predisposed to BP lability, it is possible that altered serotonin neurotransmission by pimavanserin could potentiate and exacerbate hemodynamic fluctuations.

The analysis did not identify thrombotic events as expected AEs, which DPV inquired about based on the potential for serotonergic effects on platelet function.

1.3. PIMAVANSERIN PRODUCT LABELING[20]

BOXED WARNING – Increased Mortality in Elderly Patients with Dementia-related Psychosis

Labeling for all antipsychotic products includes a boxed warning regarding the increased risk of death in elderly patients with dementia-related psychosis. The warning is based on consistent findings from 17 short-term placebo-controlled antipsychotic trials for the treatment of psychosis and agitation in patients with dementia. The boxed warning for pimavanserin and the full text of the class warning are presented below.

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at increased risk of death. NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis *[see Warnings and Precautions (5.1)].*

WARNINGS AND PRECAUTIONS

5.1 Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Antipsychotic drugs increase the all-cause risk of death in elderly patients with dementia-related psychosis. Analyses of 17 dementia-related psychosis placebo-controlled trials (modal duration of 10 weeks and largely in patients taking atypical antipsychotic drugs) revealed a risk of death in the drug-treated patients of between 1.6- to 1.7-times that in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in placebo-treated patients. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Nuplazid is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis [see Boxed Warning].

5.2 QT Interval Prolongation

Nuplazid prolongs the QT interval. The use of Nuplazid should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong QT interval including Class 1A antiarrhythmics (e.g., quinidine, procainamide) or Class 3 antiarrhythmics (e.g., amiodarone, sotalol), certain antipsychotic medications (e.g., ziprasidone, chlorpromazine, thioridazine), and certain antibiotics (e.g., gatifloxacin, moxifloxacin) [see Drug Interactions (7.1)]. Nuplazid should also be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes (TdP) and/or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and the presence of congenital prolongation of the QT interval [see Clinical Pharmacology (12.2)].

Reviewer's Comment: Pimavanserin causes significant QT prolongation, as demonstrated by a placebo-controlled, and active-controlled (moxifloxacin) dedicated thorough QT study. Details about the QT study and results are discussed below in Section 3.3.2.

DRUG INTERACTION

7.1 Drugs Having Clinically Important Interactions with NUPLAZID

Table 2 Clinically Important Drug Interactions with NUPLAZID QT Interval Prolongation	
Clinical Impact	Concomitant use of drugs that prolong the QT interval may add to the QT effects of NUPLAZID and increase the risk of cardiac arrhythmia.
Intervention	Avoid the use of NUPLAZID in combination with other drugs known to prolong QT interval *[see Warnings and Precautions (5.2)]*
Examples	Class 1A antiarrhythmics: quinidine, procainamide, disopyramide; Class 3 antiarrhythmics: amiodarone, sotalol; Antipsychotics: ziprasidone, chlorpromazine, thioridazine; Antibiotics: gatifloxacin, moxifloxacin

PHARMACCODYNAMICS – Cardiac Electrophysiology

12.2 Cardiac Electrophysiology
The effect of Nuplazid on the QTc interval was evaluated in a randomized placebo- and positive-controlled double-blind, multiple-dose parallel thorough QTc study in 252 healthy subjects. A central tendency analysis of the QTc data at steady-state demonstrated that the maximum mean change from baseline (upper bound of the two-sided 90% CI) was 13.5 (16.6) msec at a dose of twice the therapeutic dose. A pharmacokinetic-pharmacodynamic analysis with Nuplazid suggested a concentration-dependent QTc interval prolongation in the therapeutic range.

In the 6-week, placebo-controlled effectiveness studies, mean increases in QTc interval of ~5-8 msec were observed in patients receiving once-daily doses of Nuplazid 34 mg. These data are consistent with the profile observed in a thorough QT study in healthy subjects. Sporadic QTcF values ≥ 500 msec and change from baseline values ≥ 60 msec were observed in subjects treated with Nuplazid 34 mg; although the incidence was generally similar for Nuplazid and placebo groups. There were no reports of TdP or any differences from placebo in the incidence of other adverse reactions associated with delayed ventricular repolarization in studies of Nuplazid, including those patients with hallucinations and delusions associated with PDP [see Warnings and Precautions (5.2)].

2. METHODS AND MATERIALS

2.1. FAERS SEARCH STRATEGY

DPV searched the FAERS database with the strategy described in **Table 2.1.1**. See **Appendix B** for further details on additional FAERS search strategies.

Table 2.1.1. FAERS Search Strategy*

Date of Search	March 5, 2018
Time of Search	All reports through March 4, 2018
Search Type	FBIS Product-Manufacturer Reporting Summary
Product Terms	Product Active Ingredients: Pimavanserin, Pimavanserin tartrate
MedDRA Search Terms (Version 20.1)	All
Other criteria	Serious Outcome†

* See **Appendix A** for a description of the FAERS database.
† For the purposes of this review, the following outcomes qualify as serious: death, life-threatening, hospitalization (initial or prolonged), disability, congenital anomaly, required intervention and other serious important medical events.
Definitions: FBIS=FDA Business Intelligence Solution; MedDRA=Medical Dictionary for Regulatory Activity

2.2. DRUG UTILIZATION

2.2.1 Data Sources Used

Nuplazid is distributed exclusively to mail-order/specialty pharmacies (CVS, ACS, Walgreens, Accredo), specialty distributors (McKesson, AmeriscourceBergen, Cardinal, HD Smith), and is available under the Sponsor's free trial or patient assistance program (PAP), and as samples from physician offices.
As a result of this limited distribution, the proprietary drug utilization databases available to the FDA showed an incomplete capture of utilization. Therefore, an IR was sent to the Sponsor for utilization data.

The Sponsor provided FDA with the total number of tablets sold and unique patients who received a prescription for Nuplazid from U.S. mail-order and specialty pharmacies. specialty distributors, and physician offices for the aggregate time from June 2016 through March 2018. The data are stratified by patient age groups from 0-80 years in 10-year increments and 80+ years. **The drug sales and utilization data provided by the Sponsor are confidential and for internal FDA purposes only; this information cannot be released or discussed publicly without the Sponsor's approval.**

2.3. OTHER DATA SOURCES

2.3.1. Periodic Safety Reports

DPV reviewed the Periodic Adverse Drug Experience Report (PADER) No.7, October 29, 2017 to January 28, 2018.

2.3.2. Thorough QT Study

As part of the original NDA submission, the Sponsor was required to conduct a dedicated TQT study. The Sponsor conducted Protocol Number ACP-103-018 under NDA 207318. The FDA Interdisciplinary Review Team for QT Studies (QT-IRT) reviewed the study results. Dr. Li Zhang filed the QT-IRT review on October 27, 2015.

2.3.3. The Sponsor's Information Request (IR) Responses

On April 13, 2018, the Sponsor submitted a response to FDA's IR dated March 19, 2018. The FDA requested additional information on postmarketing AEs reports for pimavanserin.[23] Specifically, the FDA requested an analysis regarding AEs involving or leading to death, including:

- Cause of death
- Date of event or death
- Time to onset
- Concomitant medications (including therapy dates)
- Electrocardiogram (ECG) and laboratory results (if available)
- Physical examination (if available), and
- Any other relevant clinical information

The purpose of this IR was to attempt to better characterize fatal AE reports, and identify any clinical trends indicative of a causal relationship between fatal AEs and pimavanserin.

The Sponsor submitted an additional IR response on April 19, 2018,[24] which addressed questions FDA had regarding how the Sponsor calculated the mortality per 100 years in controlled trials submitted in the previous IR response.

The Sponsor included an update on mortality in controlled trials in an IR response on May 10, 2018.[25]

3. RESULTS

3.1. FAERS CASE SELECTION

The FAERS search retrieved 2,209 reports with serious outcomes (**Table 3.1.1**). For the purpose of this review, a detailed case-level review was not performed on all 2,209 reports. Report counts may include duplicate reports for the same patient from multiple reporters (e.g., manufacturer, family member, physician, pharmacist, nurse, etc.), miscoded reports, or unrelated reports. Reported outcomes for this section are the coded outcomes submitted to FDA; causality and the role of the product in the coded outcome have not been determined for all reports (see **Appendix A** for FAERS limitations).

We focused on cases reporting death, TdP/QT prolongation, other events of interest (e.g., seizure, CVA), off-label use, and use in patients <65 years of age in **Sections 3.1.2**, **3.1.3**, **3.1.4**, **3.1.5** and **3.1.6**, respectively.

Table 3.1.1. Descriptive Characteristics of FAERS Reports for Pimavanserin, Received by FDA through March 4, 2018

		N=2,209*
Sex	Male	1,287
	Female	672
	Not reported	250
Age	<1 to <17 years	0
	17 to <65 years	96
	>= 65 years	1,275
	Not reported	838
Country	United States	2,209
Report Type	Expedited	2,058
	Direct	94
	Periodic	57
Serious Outcomes (n=2,209)†	Death	896
	Life-threatening	10
	Hospitalization	1,069
	Disability	14
	Other serious	629

* May include duplicates

† For the purposes of this review, the following outcomes qualify as serious: death, life-threatening, hospitalization (initial or prolonged), disability, congenital anomaly, required intervention and other serious important medical events. Each report may report more than one serious outcome.

3.1.1. Most Frequently Reported MedDRA Preferred Terms (PTs)

Table 3.1.1.1. Top 50 Most Frequently Reported MedDRA PTs for Pimavanserin, Received by FDA through March 4, 2018, Sorted by Decreasing Number of FAERS Reports per PT

Row	MedDRA PT	Number of FAERS Reports*	Labeled (Yes/No), Location or Other Category†
1.	Death	614	Yes, BW and AR. See **Section 3.1.2**.
2.	Hallucination	362	Yes, AR and IR
3.	Nonspecific reaction	186	No, U
4.	Fall	185	No, DR
5.	Confusional state	173	Yes, AR
6.	Drug ineffective	130	No, U
7.	Gait inability	124	Yes, AR (Gait disturbance)
8.	Parkinson's disease	114	IR
9.	Pneumonia	113	Yes, BW
10.	Urinary tract infection	110	Yes, AR
11.	Drug dose omission	98	No, U
12.	Off label use	93	No. See **Section 3.1.3**.
13.	Prescribed underdose	93	No, U
14.	Asthenia	81	No, DR
15.	Somnolence	81	Yes, AR
16.	Aggression	79	No, DR
17.	Delusion	79	IR
18.	Abnormal behaviour	76	No, U
19.	Gait disturbance	74	Yes, AR
20.	Hospitalisation	71	No, U
21.	Agitation	62	No, DR
22.	Insomnia	57	No, DR
23.	Dysphagia	54	No, DR
24.	Dementia	50	No, DR
25.	Dehydration	49	No, DR
26.	Dysstasia	49	No, DR
27.	Nausea	48	Yes, AR
28.	Decreased appetite	47	No, DR
29.	Unresponsive to stimuli	46	Yes, AR (Somnolence)
30.	Feeling abnormal	45	No, U
31.	Peripheral swelling	44	Yes, AR
32.	Fatigue	42	Yes, AR
33.	Constipation	40	Yes, AR
34.	Balance disorder	39	Yes, AR (Gait disturbance) and DR

Table 3.1.1.1. Top 50 Most Frequently Reported MedDRA PTs for Pimavanserin, Received by FDA through March 4, 2018, Sorted by Decreasing Number of FAERS Reports per PT

Row	MedDRA PT	Number of FAERS Reports*	Labeled (Yes/No), Location or Other Category†
35.	Dizziness	39	No, CM
36.	Psychotic disorder	39	No, DR
37.	Lethargy	38	Yes, AR (Somnolence)
38.	General physical health deterioration	37	No, DR
39.	Inappropriate schedule of drug administration	37	No, U
40.	Tremor	37	No, DR
41.	Paranoia	36	No, DR
42.	Seizure	36	No. See **Section 3.1.4**.
43.	Weight decreased	36	No, DR
44.	Anxiety	34	No, DR
45.	Cerebrovascular accident	34	No. See **Section 3.1.4**.
46.	Malaise	34	Yes, AR
47.	Loss of consciousness	33	No. See **Section 3.1.3**.
48.	Hip fracture	32	No, DR
49.	Myocardial infarction	31	No. See **Section 3.1.4**.
50.	Underdose	31	No, U

* A report may contain more than one MedDRA PT.
† Definitions: BW=Box Warning; W/P=Warnings/Precautions; AR=Adverse Reactions; PCI=Patient Counseling Information; DR=Disease-related; IR=Indication-related; U=Uninformative; CM= Confounded by concomitant medications

The majority of the reported drug-event combinations were consistent with the known risks described in the labeling such as death, confusional state, gait inability/disturbance, and pneumonia, or disease related such as fall, asthenia, and dysphagia. Although increased mortality in the elderly is labeled as a part of the class Boxed Warning, we further evaluated all fatal reports in Section 3.1.2.

3.1.2. Death

The FAERS search retrieved 896 fatal reports. See **Appendix B Table 8.2.1** for the FAERS search strategy for the fatal reports. After accounting for duplicates (3), we included an analysis of the remaining 893 cases in this section. See **Appendix C** for a line listing of the 893 fatal cases. See **Section 3.1.3** for further details on cardiovascular events including QT prolongation.

Table 3.1.2.1 summarizes the 893 fatal FAERS cases (categorized by solicited cases and non-solicited cases). We considered FAERS cases as solicited cases if they were reported via specialty pharmacies or Nuplazid Connect, a patient support program for pimavanserin.

Table 3.1.2.1. Descriptive Characteristics of Fatal FAERS Cases for Pimavanserin, Received by FDA through March 4, 2018 (N=893)		
	Solicited Cases (n=657)	**Non-Solicited Cases (n=236)**
Sex		
Male	452	155
Female	204	78
Not reported	1	3
Age (years)	(n=643)	(n=225)
Mean	78	78
Range	47-97	54-89
Reasons for Use		
PDP	365	154
PD, NOS	263	53
PD with dementia	1	1
Dementia/Alzheimer's	7	10
Others*	7	3
Not reported	14	15
Duration of therapy	1 day – 19 months (n=483)	1 day – 31 months (n=170)
Time to death from initiation	(n=486) 10 days – 19 months	(n=179) 2 days – 31 months
Hospice care or advanced PD	92	46
Long term care facility	45	28
Causes of death†		
Not reported	490	157
PD	61	23
Underlying disease/Natural cause	25	0
Pneumonia	23	21
Dementia	18	5
MI/Heart attack	11	5
Respiratory failure/arrest	11	6
Cardiac Failure/CHF	7	6
Sepsis/septic shock	7	4
Cancer	6	4
Cardiac arrest	6	5
CVA	5	2
Fall	4	3
Failure to thrive	3	1
Others	14‡	8§
Concomitant medications		
Reported	283	150
Not reported	374	86
Concomitant antipsychotics†	(n=93)	(n=54)
Quetiapine	77‖	47‖
Risperidone	6	1

Table 3.1.2.1. Descriptive Characteristics of Fatal FAERS Cases for Pimavanserin, Received by FDA through March 4, 2018

(N=893)

	Solicited Cases (n=657)	Non-Solicited Cases (n=236)
Haloperidol	6	3
Olanzapine	4[‖]	2
Clozapine	2[‖]	3
Aripiprazole	1[‖]	2
Ziprasidone	1	1
Trifluoperazine	0	1

* Include psychotic disorder NOS, muscle weakness, torticollis, leukemia, progressive supernuclear palsy

[†] Each case may report more than one

[‡] Include cardiac disorder NOS (2), liver cirrhosis/failure (2), COPD (2), internal bleeding (2), blood clot NOS (1), choking (1), hypothermia (1), paradoxical reaction (1), renal injury (1), and UTI (1)

[§] Include DVT/PE (2), suicide (2), aortic dissection (1), blood clot NOS (1), organ failure NOS (2), neuroleptic malignant syndrome (1), perforated bowel (1), post-operative complication (1), renal failure (1), and UTI (1)

[‖] Include cases described stopping the antipsychotic when pimavanserin was started [quetiapine (1 solicited reports, 1 non-solicited reports), olanzapine (1), clozapine (1), aripiprazole (1)]

Definitions: MI=Myocardial infarction; CHF=Congestive heart failure; CVA=Cerebrovascular accident; COPD=Chronic obstructive pulmonary disease; DVT=Deep vein thrombosis; NOS=Not otherwise specified; PD=Parkinson's disease; PDP=Parkinson's disease psychosis; PE=Pulmonary embolism; UTI=Urinary tract infection

The majority of fatal cases were solicited cases from Nuplazid Connect or specialty pharmacies, and these cases generally did not provide enough information to assess drug-event causality. In both solicited and non-solicited cases, most patients were male with age ranging from 47 to 97 years. The most commonly reported reasons for use were PDP and PD, NOS. Patients were under hospice care or reported to have advanced/end stage PD in 140 cases [solicited (95) and non-solicited (45)]. Fatal cases reported a wide range of time-to-death after beginning treatment with pimavanserin, ranging from days to years, and taking multiple concomitant medications including antipsychotics. Among 147 cases that reported concomitant antipsychotic use, 124 cases reported use of quetiapine. Most cases did not provide a cause of death or enough clinical details for assessing any potential contributory role of pimavanserin. Among cases that provided the causes of death, the most commonly reported causes were PD progression/complication followed by "underlying disease"/ "natural cause," then pneumonia. Three cases reported autopsy results, which stated the following reasons for death: 1) "PD related;" 2) Lewy body disease, aspiration pneumonia and cardiomegaly; and 3) cardiac arrest due to coronary artery disease (CAD), hypertension, 60% restriction in the artery and peripheral arterial disease. One case coded with a fatal outcome reported "possible brain death" in a patient under palliative care after being found unresponsive on the floor and developed a pulmonary embolus (PE) while in hospital. This case did not provide further information.

We summarized two fatal cases with autopsy results and one case with limited clinical information from the case series. (See **Section 3.1.3** for the third case with autopsy results):

FAERS Case #13253411, Version 3, Expedited, Non-Solicited:

A 75-year-old male patient with PD for more than 16 years, dysphagia, and deep brain stimulator started pimavanserin for PDP. Concomitant medications included clonazepam, ibuprofen and

carbidopa/levodopa. The patient lived in a nursing home and his "state of health was poor." Five months after initiation of pimavanserin, the patient experienced dyspnea and fever, and was hospitalized for pneumonia. Four days later, the patient passed away due to pneumonia. The autopsy results stated that the cause of death was "PD related." This case did not provide any further information.

Reviewer's Comment:
This case described an elderly patient who died from pneumonia after receiving pimavanserin for five months. The patient had advanced age, long-term PD with dysphasia, and poor state of health. The most common consequences of dysphagia from PD is aspiration and pneumonia.[26] *The patient had underlying risk of pneumonia and the autopsy results showed the death was related to PD. Due to lack of clinical details and several underlying risk factors, we were not able to determine the role of pimavanserin in pneumonia and death.*

FAERS Case #13097147, Version 2, Expedited, Non-Solicited
A 72-year-old male patient with PD, dementia, and orthostatic hypotension started pimavanserin for PD, NOS. Concomitant medications included clonazepam, fludrocortisone, pravastatin, metformin, glipizide, finasteride, oxybutynin and carbidopa/levodopa. On an unspecified date (same year pimavanserin was initiated), the patient passed away. The patient had encephalopathy delirium prior to death and the autopsy results showed Lewy body disease, aspiration pneumonia and cardiomegaly. This case did not provide any further information.

Reviewer's Comment:
This case described an elderly patient who died from Lewy body disease, aspiration pneumonia and cardiomegaly after receiving pimavanserin for an unknown period of time. The patient had advanced age, multiple comorbidities and multiple concomitant medications. Due to lack of clinical details and several underlying risk factors, we were not able to determine the role of pimavanserin in pneumonia and death.

FAERS Case #13880412, Version 3, Expedited, Solicited
A 46-year-old male was hospitalized for an unspecified reason six months after initiating pimavanserin 34 mg once daily for PD. The patient had "spiked fevers" and had "shakes" while hospitalized, and passed away from "complication of illness" (unspecified) 113 days from date of hospitalization. Despite three follow-up attempts by the Sponsor, limited additional clinical information was obtained.

Reviewer's Comment:
This case described a PD patient who died from unspecified "complication of illness." Due to lack of clinical details, we were not able to determine the role of pimavanserin in "complication of illness" and death.

3.1.3. Cardiovascular Events, TdP, and QT Prolongation FAERS Cases

We searched the FAERS database to capture deaths and other serious cardiovascular events potentially related to pimavanserin and QT prolongation. Refer to **Appendix B Table 8.2.2** for further details on the FAERS search strategy for these cases. **Table 3.1.3.1** presents all of the

Preferred Terms (PTs) in the Torsade de Pointes/QT Prolongation Standardised Medical Dictionary for Regulatory Activities (MedDRA) Query (SMQ) and the number of unique FAERS cases retrieved in the search for each term. The search captured 91 FAERS reports, including duplicates (3), for a total of 88 unique patient cases. See **Appendix D** for a line listing of the 88 cases. There were 83 SAE cases and 5 non-SAE cases. The most common PTs captured by the search were: *Loss of consciousness* (n=34), *Electrocardiogram QT prolonged* (23), *Cardiac arrest* (15), and *Syncope* (13). There were no cases reporting TdP or any type of ventricular arrhythmia. A higher proportion of cases were solicited (67%) than reported spontaneously (33%).

Table 3.1.3.1. Reported MedDRA PTs in Torsade de Pointes/QT Prolongation SMQ (Broad) for Pimavanserin, Received by FDA through March 4, 2018

MedDRA PTs in SMQ	Total Number FAERS Cases N=88 (Fatal=25)	Solicited Cases N=58 (Fatal=15)	Non-Solicited Cases N=30 (Fatal=10)
Loss of Consciousness	32 (3)	25 (2)	7 (1)
Electrocardiogram QT prolonged	23	14	9
Cardiac Arrest	15 (14)	8 (8)	7 (6)
Syncope	13 (3)	7 (1)	6 (2)
Cardio-respiratory Arrest	3 (3)	2 (2)	1 (1)
Sudden cardiac death	1 (1)	1 (1)	0
Sudden death	1 (1)	1 (1)	0

Generally, the patients with PDP in these cases had advanced Parkinson's disease and were elderly. The mean age was 80.4 years, and the age range was 54 to 92 years. Patients commonly had numerous medical comorbidities that are significant risk factors for death and SAEs. These included: cardiovascular disease (e.g., CAD, MI, congestive heart failure, PE, abdominal aortic aneurysm [AAA], atrial fibrillation), cerebrovascular disease, dementia, chronic pulmonary disease, diabetes mellitus, chronic kidney disease, neurogenic orthostatic hypotension, autonomic instability, neoplasms, and serious infection (e.g., pneumonia, urosepsis). Many patients were treated concomitantly with antipsychotics (e.g., quetiapine) or antidepressants (e.g., escitalopram, fluoxetine) that can prolong the QT interval. Numerous patients were concomitantly treated with diuretics, which can cause electrolyte disturbances and increase the risk of QT prolongation. Furthermore, antipsychotic treatment may increase the risk of all-cause mortality in patients with PD and elderly patients with dementia.

A high proportion of these FAERS cases had limited information regarding the specific AEs, potential temporal relationships between pimavanserin treatment and AEs, medical history and risk factors, concomitant medications, and clear documentation of actual exposure to pimavanserin. Several solicited cases either confirmed that patients had not actually begun treatment with pimavanserin, or there was uncertainty about whether the patient had begun treatment. Only one case reported autopsy results to confirm a cause of death; additional details of this case are provided in **Section 3.1.3.1**. Thus, most cases were difficult to interpret and

confirm or rule out a causal relationship with pimavanserin. Moreover, because many of the potential cardiovascular events and deaths were unwitnessed and not monitored with ECG, it was difficult to adjudicate events. In addition, potential syncopal events and loss of consciousness (LOC) events are typically difficult to diagnose initially, and often require detailed further investigation for attributing a causal mechanism.

There were 25 deaths captured under the following PTs in the relevant SMQ: *Cardiac arrest* (14), *Cardiopulmonary arrest* (3), *Sudden cardiac death* (1), and *Sudden death* (1). Six fatal cases were captured under the PTs *Loss of consciousness* (3) and *Syncope* (3); the probable causes of death in these cases were: esophageal cancer (1), PE (1), pneumonia (1), stroke (1), CVA and seizure (1), CVA and pneumonia (1). None of the fatal cases reported TdP, other ventricular arrhythmia, or QT prolongation. In some fatal cases, the patients were found deceased after unknown periods during which they were not observed. There was one case reporting pulseless electrical activity (PEA) in a patient with a history of AAA, possibly consistent with a dissecting AAA. In other fatal cases, likely causes of death or major contributing factors included: MI, PE, vena cava thrombosis, congestive heart failure, CVA, esophageal cancer, pneumonia, end-stage renal failure and death during dialysis, and possible post-surgical complications after hip fracture.

3.1.3.1. Representative FAERS Cases of Sudden Death or Cardiac Arrest

FAERS Case #13814966, Version 2, Expedited, Solicited (Nuplazid Connect)
PTs *Sudden cardiac death, Nausea, Dizziness, Hallucination, Hypersomnia*
The information was provided by the patient's daughter. The patient was an 81-year-old female with a diagnosis of PDP, with hallucinations and delusions for about two years. The patient had a hip fracture and surgery four weeks previously. Concomitant medications included quetiapine, escitalopram, carbidopa/levodopa, and aspirin. There was no other reported medical history. On Day 1, the patient began treatment with pimavanserin 34 mg daily. The following day (Day 2 of treatment), the patient awoke with severe nausea. The daughter also noted that "she did sleep a lot that night before and did not feel well." The patient died suddenly on Day 2 in her home. It is not clear whether she had taken a second pimavanserin dose. The daughter stated that the death was sudden and unexpected and that her mother was not ill. She reported that the physicians "think that it could have been a sudden heart issue," but an autopsy was not performed. The family thought the death and other AEs were possibly related to pimavanserin. There was no other clinical information provided.

Reviewer's Comment: This appears to be a well-documented case of sudden death. Although there were no confirmatory ECG data or autopsy data, it appears likely that this was a primary cardiac event; there was no reported evidence of significant non-cardiac disease, and the patient was elderly. However, there is considerable missing information about whether the patient had risk factors such as previously diagnosed or undiagnosed cardiovascular disease, arrhythmia, pulmonary, or other disease. The events could be consistent with a serious cardiac event related to QT prolongation. The patient was treated with three medications that can prolong the QT interval: pimavanserin, quetiapine, and escitalopram. Although not apparently diagnosed or treated for CHD (a risk factor for sudden cardiac death), the patient was elderly, had PDP, and possibly had significant underlying disease such as CAD, hypertension, etc.

FAERS Case #13868124, Version 2, Expedited, Solicited (Nuplazid Connect)
PTs *Sudden death, Somnolence*
The information was provided by the patient's husband and daughter. The patient was a 76-year-old female with a diagnosis of PDP with hallucinations and delusions. She started pimavanserin 34 mg daily and was treated for approximately five months. Throughout treatment, the patient reported excessive sedation ("need to nap and feel very groggy"). On an unknown date after discontinuing pimavanserin, the patient reportedly went to the hospital for a routine visit but was quickly admitted to an intensive care unit and died. The patient's daughter reported that "it was a sudden passing." There were no other details regarding past medical history, concomitant medications, hospital course, or other AEs. There was no reported autopsy or stated cause of death.

Reviewer's Comment: Important clinical information was missing regarding specific AEs, past cardiac or other medical history, and concomitant medications that could have been risk factors for the death. It was not possible to confirm or rule out a causal role for pimavanserin. However, it seems unlikely that pimavanserin contributed to the death, because of the long latency after beginning pimavanserin, and pimavanserin was discontinued before the fatal events.

FAERS Case #12507321, Version 3, Expedited, Non-Solicited
PTs *Cardiac arrest, Arrhythmia, Coronary artery occlusion, Hypertension, Hypertensive angiopathy, Peripheral arterial occlusive disease, Somnolence*
The information was provided by the patient's family and physician. The patient was a 73-year-old female in a long-term care facility, with PDP with hallucinations and delusions, dementia, hypertension, orthostatic hypotension, colitis, urinary incontinence, and gastroparesis. Concomitant medications included domperidone, carbidopa/levodopa, aspirin, ramipril, valproate, midodrine, polyethylene glycol (PEG) 3350, galantamine, and levothyroxine. The patient began treatment with pimavanserin 34 mg daily on either Day 1 or Day 2 (there are conflicting reports). The dose was decreased to 17 mg on Day 2 or Day 3. On Day 4 at 7:55 AM, the patient was ambulating but reported feeling sedated. Later in the morning, the patient was found unresponsive and pulseless, underwent cardiopulmonary resuscitation (CPR) and resuscitative efforts, and was pronounced dead at 8:34 AM. The autopsy report stated that the cause of death was primary cardiac arrest secondary to CAD. It was reported that the autopsy results further stated that the cause of death was "atherosclerotic and hypertensive cardiovascular disease with terminal/fatal arrhythmia," with 2-vessel disease, slight cardiomegaly, bi-ventricular dilatation, and left ventricular hypertrophy, consistent with sudden terminal fatal cardiac arrhythmia. The proximal left anterior descending (LAD) coronary artery had 80-90% occlusion, and the right coronary arteries had 60-70% occlusion. There was no recent or healing coronary artery thrombus, and the myocardium was homogenous, dark-red, and firm without pallor, hemorrhagic infarction, or softening. There was no evidence of congestive heart failure, PE, or cerebral infarction. Neuropathology was consistent with idiopathic PD, with no evidence of Alzheimer's disease or Lewy body dementia.

Reviewer's Comment: Dr. Daniel Woronow, cardiologist in DPV, reviewed this case. Dr. Woronow concluded that it is possible that pimavanserin contributed to cardiac arrest and sudden death in this case, as suggested by the short time to onset of events (2-4 days) after

initiating pimavanserin and other features consistent with primary cardiac events. The immediate cause of death was likely a non-infarct related ventricular cardiac arrhythmia (although, there were no ECG data reported). The autopsy findings do not seem to demonstrate evidence of a significant MI related to the patient's death. The autopsy is consistent with pre-existing CAD and pre-existing left ventricular dysfunction, which are risk factors for fatal ventricular arrhythmia (i.e., sudden death). This patient had a "widow(er) maker" 80-90% stenosis of the proximal LAD coronary artery. Concomitant medications included domperidone, which causes QT prolongation. In Canadian product labeling, domperidone has a Boxed Warning for serious ventricular arrhythmias or sudden cardiac death. In the U.S., domperidone is available under an investigational drug (IND) protocol only. The patient's death could have been related to her underlying heart disease, domperidone, pimavanserin, or a combination of these arrhythmia risk factors.

FAERS Case #12615218, Version 2, Expedited, Non-Solicited

PTs *Cardiac arrest, Pulseless electrical activity, Respiratory failure*

This was an 89-year-old female with a diagnosis of PDP with auditory and visual hallucinations. A physician provided follow-up information. The patient was treated with pimavanserin 34 mg daily for 10 or 11 days. Past medical history included CAD, abdominal aortic aneurysm (AAA), hypertension, pacemaker placement, atrial fibrillation, diabetes mellitus, asthma, COPD, hypothyroidism, gastroesophageal reflux disease (GERD). There were numerous concomitant medications including ondansetron, formoterol, digoxin, diltiazem, hydrocodone/acetaminophen, potassium, insulin, dofetilide, torsemide, warfarin, valsartan, prochlorperazine, and nebivolol. The patient had a witnessed arrest in a nursing home, and presented to the emergency room (ER) in cardiac arrest, found to have pulseless electrical activity (PEA) and wide complex tachycardia. The patient had full resuscitative efforts, including CPR, five doses of epinephrine, and intubation.

Reviewer's Comment: Dr. Woronow concluded that multiple medications and disease-related factors likely contributed to the patient's demise. There is no evidence that pimavanserin contributed directly to the patient's death; however, it is possible that pimavanserin could have contributed through QT-prolonging effects. Dofetilide is a TdP/QT prolonging drug. The combination of digoxin and dofetilide is concerning. The dofetilide labeling in the Potential Drug Interactions section states "the concomitant administration of digoxin with dofetilide was associated with a higher occurrence of Torsade de Pointes." However, "No increase in mortality was observed in patients taking digoxin as concomitant medication" (with dofetilide). The concomitant use of diltiazem and nebivolol may have additional pharmacodynamic effects, although these should be ameliorated by the patient's pacemaker. In general, pacemaker therapy may be somewhat protective against TdP. Ondansetron is also associated with TdP/QT prolongation. Formoterol has QT effects and has labeling for QT prolongation. The patient was on a torsemide diuretic and several potassium-affecting drugs, which could also contribute to TdP or other ventricular arrhythmias.

The patient's initial cardiac event was PEA. Electrical pacemaker activity in an asystolic patient can be mistaken for PEA. Medical history included AAA, which may have ruptured and caused undetected massive internal hemorrhage leading to PEA. A respiratory arrest and hypoxia may have preceded the PEA. PE leading to PEA is less likely in this warfarin-treated patient.

Apparently, the ER staff was able to obtain a wide complex tachycardia after multiple doses of epinephrine, which is a common sequela in this type of resuscitation attempt scenario.

This patient also had a history of CAD, as would be expected with the multiple risk factors and advanced age. MI is a common cause of death in such patients.

FAERS Case #14239437, Version 1, Expedited, Solicited (Nuplazid Connect)
PTs *Cardiac arrest, Circulatory collapse*
This was a 74-year-old female with PDP, hallucinations and delusions. The only past medical history provided was that the patient had been on dialysis during the fatal event. The report stated that the patient collapsed during dialysis, went into cardiac arrest, was taken to hospital, and died. The cause of death was reported as cardiac arrest. Prior to hospitalization, the patient was living at home. No additional information was reported. It could not be confirmed whether the patient had begun treatment with pimavanserin; the first medication shipment was reportedly received six days prior to the event, and the second was received on the day of the event.

Reviewer's Comment: It is difficult to assess the cause of death or potential role of pimavanserin, because of limited clinical information about the current and past medical history, medication history, and uncertainty about actual exposure to pimavanserin. It is not uncommon for dialysis patients to experience sudden cardiac arrest or circulatory collapse secondary to complications of end-stage renal failure and hemodialysis. The risk of sudden cardiac death is high in patients with chronic kidney disease.[27] The most common causes are ventricular tachycardia, ventricular tachyarrhythmia, TdP, sustained ventricular fibrillation, and bradyarrhythmia. Dialysis has important cardiovascular effects that can cause hemodynamic and electrolyte disturbances and affect myocardial electrophysiology. Dialysis can increase vulnerability to serious arrhythmia through sudden shifts in fluid status and electrolytes, particularly potassium and calcium.

As illustrated in the FAERS cases in Section 3.1.3.1, most of the sudden cardiac death (SCD) and sudden cardiac arrest (SCA) cases did not involve witnessed events, and no patients had ECG monitoring before the events occurred. Thus, it was not possible to determine the precise cause of death or determine whether pimavanserin had a causal role in the events. The causal mechanism(s) can only be inferred, based upon information obtained after the event; however, in these FAERS cases, clinical information was usually limited.

SCD is a common cause of death, accounting for approximately 15% of total mortality in the U.S.[28] The incidence of SCD and SCA increase dramatically with age and underlying cardiac disease. All patients in these SCD and SCA cases were elderly and had cardiovascular or other risk factors for sudden fatal events which included: CHD, AAA, hypertension, concomitant hemodialysis, treatment with QT interval-prolonging drugs, and advanced age. Most risk factors for CHD are also risk factors for SCA. SCA and SCD typically occur secondary to sustained ventricular tachycardia or ventricular fibrillation.[29] These events mostly occur in patients with structural cardiac disease, particularly coronary heart disease (CHD).[30] Approximately 65% to 70% of all SCDs are attributable to CHD. In several cases of SCD, it is possible that pimavanserin contributed to the fatal events, particularly if there was QT prolongation and ventricular arrhythmia; however, none of these cases involved ECG documentation of QT

prolongation. Furthermore, there are many cardiac and noncardiac causes for a sustained ventricular tachyarrhythmia that can result in sudden death; approximately 15% to 25% of cardiac arrests are noncardiac in origin.

3.1.3.2. Representative FAER Cases Reporting QT Interval Prolongation

FAERS Case #13136975, Version 1, Expedited, Non-Solicited
PTs *ECG QT prolonged, Bradycardia, Blood pressure decreased, Encephalopathy*
The information was provided by a medical technician, with follow-up from a physician. The patient was a 79-year-old male with PDP, treated with pimavanserin 34 mg daily. Concomitant medications included carbidopa/levodopa, oxybutynin, and PEG 3350. No other medical history was provided. The reporter stated that the "blood pressure was very low and patient was really out of it and pulse was 45." Pimavanserin was discontinued on Day 11 of treatment because of hypotension (75/55 mmHg). The patient's BP reportedly returned to baseline. The physician reported that the patient experienced bradycardia and encephalopathy, and the patient's condition improved on Day 11. The ECG reportedly demonstrated "sinus bradycardia with prolonged QT interval." There were no numerical ECG data or baseline ECG for comparison. The physician and technician considered the AEs related to pimavanserin.

Reviewer's Comment: There was limited clinical information available for this case. It is possible that pimavanserin contributed to encephalopathy. Pimavanserin is not known to cause hypotension; however, it is possible that pimavanserin could cause BP lability through its serotonergic effects. It is possible that pimavanserin caused QT prolongation in this case.

FAERS Case #13245830, Version 3, Expedited, Non-Solicited
PTs *ECG QT prolonged, Myocardial infarction, Palpitations, Chest pain, Confusional state*
The information was provided by the patient's daughter. The patient was an 85-year-old male with a diagnosis of PD, dementia, and possibly Lewy body disease, treated with pimavanserin 34 mg for approximately three months. Concomitant medications included escitalopram, spironolactone, propranolol, carbidopa/levodopa, aspirin, warfarin, ibuprofen, mirabegron, paroxetine, donepezil, and gabapentin. Several weeks after beginning pimavanserin, the patient experienced an increase in heart rate and chest pain. An ECG reportedly demonstrated QT prolongation; however, the reporter stated that it was uncertain whether this had existed prior to treatment with pimavanserin. No additional ECG data were reported. The physician decided to discontinue pimavanserin because of concern about QT prolongation. Approximately one to two months after discontinuing pimavanserin, the patient had an MI

Reviewer's Comment: The patient had several risk factors for QT prolongation, including pimavanserin, escitalopram, and donepezil. However, because of limited information, it is not clear that the patient had an increase in QT interval after beginning pimavanserin. It is possible that CHD and ischemia contributed to the events.

FAERS Case #13252867, Version 1, Non-Expedited, Non-Solicited
PTs Electrocardiogram QT prolonged, Delusion, Hallucination
The information was provided by a 78-year-old male patient with PDP, delusions, and memory impairment. A physician provided follow-up information. The patient stated that he "didn't like

the way his heart was functioning" during treatment with pimavanserin 34 mg daily. Significant medical history included congestive heart failure and dilated cardiomyopathy. The patient's concomitant medications included donepezil, memantine, and amantadine. The reported pre-pimavanserin QT interval was 342 ms. Approximately two weeks after beginning pimavanserin, the QT interval was 420 ms. Reportedly the patient's cardiologist concluded that the patient had QT prolongation, and discontinued pimavanserin.

Reviewer's Comment: It is possible that pimavanserin caused or contributed to QT interval prolongation. However, there were numerous additional risk factors for QT prolongation, including: donepezil, amantadine, and underlying heart disease (cardiomyopathy, heart failure, and possibly CHD).

There were 23 FAERS cases containing the PT *Electrocardiogram QT Prolongation*. None of these cases were fatal or involved documented TdP or other ventricular arrhythmia. Most reports were not clinically confirmed as actual cases of QT prolongation. Most reports had sparse information and did not include actual ECG data regarding a measured QT interval. Only one case reported a numerical QT value, and only one case referred to a baseline ECG before beginning treatment with pimavanserin. Most of the QT cases were solicited, in which a family member stated that the patient apparently had an episode of QT prolongation. In two solicited cases, family members expressed concern about the potential for QT prolongation with pimavanserin, but they did not state that the patient experienced QT prolongation.

In some cases, health care professionals reported that patients had experienced QT prolongation, but most did not include ECG data or make reference to a pre-treatment ECG. None of the cases reported symptoms that could be attributed to QT prolongation; and several clinicians specifically noted that patients were asymptomatic, and the ECGs were performed for non-specific reasons (e.g., routine scheduled ECGs, or for insurance purposes). In several cases, pimavanserin was continued because it was reportedly providing benefit; however, some cases reported discontinuation of pimavanserin or dose reduction because of QT prolongation.

There were numerous concomitant medications in the cases that could have contributed to drug-drug interactions and QT prolongation, through pharmacodynamic or pharmacokinetic effects. As noted, numerous patients were treated concomitantly with antipsychotics that can prolong the QT interval and have QT warnings: quetiapine, clozapine, asenapine, paliperidone, and iloperidone. Some were treated with the antidepressant, citalopram, which can cause QT prolongation. These drugs are not currently listed in the pimavanserin label. Several of these patients were also treated with diuretics, increasing the risk of electrolyte abnormalities, QT prolongation, and serious cardiovascular AEs. Many of these patients had treatment with supplemental potassium, probably indicating that they had a history of hypokalemia or were considered at significant risk of developing hypokalemia. Diuretic treatment is also a risk factor because of its correlation with heart failure, as well as direct blockade of potassium current by some diuretics.[31] Bradycardia is an additional risk factor for QT prolongation, which may be related to a fall in local extracellular potassium concentration, leading to enhanced drug-induced inhibition of IKr (rapidly activating delayed rectifier potassium channel). In none of the cases could it be established that pimavanserin alone contributed to QT prolongation, and in many

cases, it could not be confirmed that patients actually had QT prolongation compared to their pre-treatment state.

3.1.3.3. Representative Cases of Syncope or Loss of Consciousness

FAERS Case #12938564, Version 3, Expedited, Non-Solicited
PTs *Syncope, Pulmonary thrombosis, Vena cava thrombosis, Fall*
The patient was a 75-year-old female with PDP. Concomitant medications were citalopram and carbidopa/levodopa. Pimavanserin 34 mg daily was started on Day 1. The report was received on Day 42. On an unspecified date and duration of pimavanserin treatment, the patient was hospitalized secondary to "two fainting spells." These events are not described further. The patient was found to have pulmonary thrombosis and vena cava thrombosis. The patient was treated with tissue plasminogen activator. No other information was provided.

Reviewer's Comment: The case contained limited information. It is not possible to establish a diagnosis for the episode or a relationship between the AEs and treatment with pimavanserin. Pulmonary thrombosis and vena cava thrombosis possibly contributed to the events considered "fainting spells."

FAERS Case #13005355, Version 2, Expedited, Non-Solicited
PTs *Syncope, Narcolepsy*
This was submitted by a patient who was a 54-year-old female with psychotic disorder and hallucinations. Medications included ondansetron, tizanidine, tramadol, topiramate, hydrocodone, insulin, metoprolol, clonazepam, gabapentin, and donepezil. No other medical history was provided. The patient was treated with pimavanserin 34 mg for approximately one month. The patient stated that pimavanserin caused her to be "narcoleptic" and that she would frequently "fall asleep at the drop of a hat" and have numerous "fainting spells." The patient stated that she was not evaluated for the episodes. She decreased her dose to 17 mg, without resolution of sedation. After discontinuing pimavanserin, the sedation and fainting spells resolved.

Reviewer's Comment: It does not seem likely that these are actually syncopal episodes, rather than excessive sedation; however, the possibility that these are syncopal episodes cannot be ruled out. Several of the patient's medications can cause QT prolongation, including pimavanserin, ondansetron, and donepezil. The patient was treated with numerous drugs that can cause sedation and central nervous system (CNS) depression: tramadol, hydrocodone, topiramate, clonazepam, gabapentin. Pimavanserin can also cause sedation and CNS toxicity, including confusional state and probably encephalopathy and delirium. It is difficult to determine a diagnosis of her condition; the differential diagnosis includes at minimum: syncope, presyncope, sedation, general CNS depression, arrhythmia, and hypotension.

FAERS Case #12938025, Version 1, Non-Expedited, Non-Solicited
PTs Syncope, Heart rate decreased
This was a non-serious case submitted by the patient's nurse. The patient was an 81-year-old female with a diagnosis of PDP, hallucinations and delusions. She was treated with pimavanserin

34 mg for approximately three or four days. Other medical history and medication history were not provided. The nurse reported that the patient had experienced a syncopal episode and decreased heart rate while treated with pimavanserin. No other details were provided.

Reviewer's Comment: No other information was provided about the events or medical history. It is possible that this was a syncopal episode or another type of event related to LOC. There is a broad differential diagnosis for such events. It is possible that pimavanserin could have contributed through QT interval prolongation; however, there is no supportive information available. This is a representative case illustrating the limited information provided and resultant difficulty in assessing the potential role of pimavanserin.

FAERS Case #12703527, Version 2, Expedited, Non-Solicited

PTs *Loss of consciousness, Encephalopathy, Gait inability, Aphasia, Loss of personal independence in daily activities*

The patient was a 61-year-old male with PDP, dementia, hallucinations, and delusions, treated with pimavanserin 34 mg daily. On Day 1 of pimavanserin treatment, the patient was "knocked out cold, could not talk, couldn't feed himself or walk." Pimavanserin was discontinued because of these AEs. Concomitant medications included donepezil, carbidopa/levodopa, memantine, and rotigotine.

Reviewer's Comment: With the limited information, it is not possible to establish whether the event consisted of a LOC, or whether the events are more consistent with encephalopathy, delirium, profound CNS depression, or some other type of CNS event impacting cognitive and motor function. Pimavanserin can cause confusional states, sedation, and possibly encephalopathy and delirium. Given the apparent acuity and short time to onset relative to beginning treatment with pimavanserin, it is possible that pimavanserin caused or contributed to the CNS AEs.

Syncope is defined as a transient loss of consciousness (TLOC) caused by a period of inadequate cerebral nutrient flow, most often caused by an abrupt drop of systemic BP.[32] Syncope is only one of many potential causes of TLOC. True syncope itself has many possible causes, and there is a broad differential for diagnosing events consistent with TLOC, and distinguishing these conditions from true syncope may be challenging. The causes of TLOC resulting in syncope are grouped into 4 major categories: 1) neurally-mediated reflex syncope; 2) Orthostatic syncope; 3) Cardiac arrhythmias; and 4) Structural cardiopulmonary disease. The evaluation of suspected syncope relies heavily on obtaining a comprehensive history, performing a physical examination, and reviewing an ECG.[33]

In the FAERS cases coded with the PTs *Syncope* and *Loss of consciousness*, information was typically limited regarding the nature of the events, preceding events, medical history, additional potential risk factors, duration of the event, mental status examination, cardiac exam, or ECG. Thus, diagnosis and causality assessment were limited for most of the relevant FAERS cases. In addition, many patients experiencing TLOC or syncope have multiple co-morbidities that can contribute to TLOC; the PDP patient in these cases generally had numerous relevant medical conditions and medications. Thus, there may have been multiple plausible causes.

Most of these FAERS cases did not appear to include primary cardiac events; however, some appeared to be consistent with LOC. There were no reports of abrupt falls or injuries after fall or LOC. In numerous cases, it appeared that the patient had not fully lost consciousness; rather, it appeared that patients had experienced significant acute changes in mental status, which appeared more consistent with encephalopathy, confusional states, delirium, fluctuation in level of consciousness, or profound CNS depression or sedation, often accompanied by significant motor or speech impairment, and general incapacitation. Numerous (13) cases involving similar events were reported as "catatonia." In fact, pimavanserin was demonstrated in placebo-controlled trials to cause confusional states, hallucinations, and gait disturbance, at higher rates than in the placebo group. In addition, the following CNS postmarketing AEs have been reported very commonly during treatment with pimavanserin: *Fall, Confusional state, Gait inability, Asthenia, Somnolence, Abnormal behavior, Unresponsive to stimuli, Loss of consciousness, Immobile, Speech disorder, Delirium, Coma, Catatonia, Encephalopathy*. Because of the typical challenges with interpreting FAERS reports, it is not currently possible to conclude that all of these events were related to pimavanserin; however, it is possible that pimavanserin may increase the risks of these CNS events.

In most cases coded with the PTs Syncope or Loss of Consciousness, there was not a clear temporal relationship between the events and pimavanserin initiation to strongly suggest that pimavanserin was a causal factor. In addition, numerous patients had pre-existing major risk factors for syncope and pre-syncope, including orthostatic hypotension and treatment for orthostasis, autonomic instability, and diabetes mellitus. Similarly, patients with advanced PD and PDP are at high risk for falls, changes in mental status, sedation, and confusional states, secondary to their primary neurologic illness and medication treatments for PD and co-morbid conditions. Thus, many of these patients had numerous risk factors for events coded as syncope or LOC.

It is possible that some of the syncope or LOC AEs were related to treatment with pimavanserin, secondary to QT interval prolongation and arrhythmia; however, QT prolongation and arrhythmia were not reported in these cases. In addition, it is possible that some syncopal and pre-syncopal events could be related to pimavanserin through mechanisms causing autonomic instability (e.g., BP decreases and bradycardia). It appears that some events coded as syncope or LOC were not actually syncopal or LOC events, but were more consistent with encephalopathy or delirium, without full LOC. Some of these events appeared to be related to pimavanserin, based on temporal relationships, acute onset of events, and the premarketing findings of increased rates of confusional states with pimavanserin, compared to placebo.

3.1.4. Other Events of Interest

The FAERS search retrieved 112 reports for seizure, CVA, MI, or venous thromboembolism (VTE). See **Appendix B Table 8.2.3** for the FAERS search strategy for these cases. After accounting for duplicates (2) and excluding overlapping reports from **Sections 3.1.2** (38) and **3.3.2** (5), we included 67 cases in this section. **Table 3.1.4.1** summarizes 67 FAERS cases reporting non-fatal seizure, CVA, MI or VTE. See **Appendix E** for a line listing of these 67 cases.

Table 3.1.4.1. Descriptive Characteristics of Non-Fatal FAERS Cases reporting Seizure, CVA, MI or VTE for Pimavanserin, Received by FDA through March 4, 2018 (n=67)

	Seizure (n=27)	CVA (n=21)	MI (n=8)	VTE (n=11)
Sex				
Male	18	11	5	5
Female	8	10	2	6
Not reported	1	0	1	0
Age (years)	(n=25)			
Mean	76.9	79.9	74.2	72.5
Range	57-90	63-93	65-82	60-81
Duration of therapy	(n=10) 2 days- 2 months	(n=6) 3 days- 1.5 months	(n=3) 2 weeks – 6 months	(n=2) 11 days - ≤1 month
Time to onset from initiation	(n=19) Same day- 5 months	(n=18) 3 days- 6 months	(n=7) 7 days- 6 months	(n=9) 7 days – 14 months
Other risk factors				
Medical history of the event	2	0	1	1
Risk factors for the event	0	5†	0	4‡
Use of concomitant medication labeled for the event	16*	0	0	0

* Each case may report more than one: carbidopa/levodopa (9), quetiapine (6), donepezil (3), alprazolam (2), mirtazapine (2), sertraline (2), trazodone (2), aripiprazole (1), citalopram (1), fluoxetine (1), methylphenidate (1), paroxetine (1), perphenazine (1), rivastigmine (2), trihexyphenidyl (1)

† Include MI (1), atrial fibrillation/heart arrhythmias (2), aortic valve replacement (1), cancer (1)

‡ Include essential thrombocytosis (1), immobilization (3)

Definitions: CVA=Cerebrovascular Accident; MI=Myocardial infarction; VTE=Venous thromboembolism

For non-fatal cases reporting seizure, CVA, MI, or VTE [DVT (3), PE (6), both DVT and PE (2)], the majority of cases were solicited cases [solicited cases (44) and non-solicited cases (23)] and did not provide enough information to assess drug-event causality. Most patients were male with an age range of 57 to 93 years. Some cases reported past medical history, risk factors for the events of interest, or concomitant use of medications labeled for the event of interest. Duration of therapy and time–to-onset of event after beginning pimavanserin treatment ranged from days to months.

We summarized cases that provided the most information reporting seizure, CVA, MI or VTE from the case series.

FAERS Case #13025415, Version 1, Expedited, Non-Solicited

A 57-year-old female with an unknown medical history started pimavanserin for PDP. After two doses of pimavanserin, the patient experienced a seizure. Pimavanserin was discontinued, and quetiapine was weaned off at the same time. This case did not provide further information.

Reviewer's Comment:
This case reported seizure in a patient who received two doses of pimavanserin. Due to concomitant use of a medication labeled for seizure and lack of clinical details, including medical history, we were not able to determine the role of pimavanserin in the seizure.

FAERS Case #13867553, Version 3, Expedited, Solicited
A 77-year-old male with a history of aortic aneurysms and aortic valve replacement started pimavanserin for PDP. Two months later, the patient was admitted to a hospital due to a stroke. The patient was discharged on an unspecified date. This case did not provide further information.

Reviewer's Comment:
This case reported stroke in a patient who used pimavanserin for 2 months. The patient had a history of aortic valve replacement, which is a risk factor for developing stroke. Due to the underlying risk for stroke and a lack of clinical details, we were not able to determine the role of pimavanserin in the stroke.

FAERS Case #13743318, Version 1, Expedited, Solicited
A 73-year-old male with a history of nose bleed started pimavanserin for PDP. About three weeks later, the patient experienced chest pain and hypertension, and was admitted to the hospital overnight. The patient had "borderline first degree heart block on ECG" and received Nitropaste. Three days later, the patient experienced chest pain again with arm/shoulder pain. The patient had a "heart attack" and was admitted to hospital. The patient was discharged after five days. This case did not provide further information.

Reviewer's Comment:
This case reported a "heart attack" in a patient who received pimavanserin for about three weeks. This case did not provide information regarding past medical history other than nose bleed, or a list of concomitant medications. Due to lack of clinical details, we were not able to determine the role of pimavanserin in the event.

FAERS Case #13386105, Version 2, Expedited, Solicited
A 64-year-old male with a history of hypertension and hyperlipidemia started pimavanserin for PD. About a month later, the patient presented to the hospital with chest pain and shortness of breath, and was found to have bilateral popliteal DVT and bilateral PE with mild right-sided heart strain and demand ischemia. The patient was started on rivaroxaban and discharged to a nursing home seven days after hospital admission.

Reviewer's Comment:
This case reported DVT and PE in a patient who received pimavanserin for about one month. This case did not provide information regarding risk factors for DVT/PE such as family history, smoking status, prolonged bed rest or acute injury. Due to lack of clinical details, we were not able to determine the role of pimavanserin in the DVT/PE.

3.1.5. Off-Label Use

The FAERS search retrieved 93 reports coded with the PT *Off label use*. See **Appendix B Table 8.2.4** for the FAERS search strategy. After accounting for duplicates (1) and excluding cases reporting PDP as the reason for use (45), 47 cases were included in this section (categorized by PD, NOS and non-PD). Note: In an effort to provide the full description of cases with the PT *Off label use*, overlapping cases from other sections of this review were not excluded. See **Appendix F** for a line listing of these 47 cases.

Table 3.1.5.1. Descriptive Characteristics of FAERS Cases with PT *Off label use* for Pimavanserin, Received by FDA through March 4, 2018 (N=47)

	PD, NOS (n=12)	**Non-PD (n=35)**
Sex		
Male	10	19
Female	2	16
Age (years)	(n=11)	(n=34)
Mean	71	74
Range	49-85	47-95
Reasons for Use*	(n=12)	(n=35)
PD	12	0
Dementia	7	19
Alzheimer's	1	3
Generalized psychotic/Mental disorder	0	7
Hallucination, NOS	0	2
Others†	0	5
Serious Outcome*‡	(n=12)	(n=35)
Death§	4	19
Hospitalized	5	13
Other Serious	7	12
Causes of death§	(n=4)	(n=19)
Not reported	3	13
Underlying disease/Natural cause	0	3
COPD	1	0
Liver failure	0	1
MI/Heart attack	0	1
Pneumonia	0	1
Concomitant medications		
Reported	10	23
Not reported	2	12
Concomitant antipsychotic*	(n= 6)	(n=7)
Quetiapine	5	3
Risperidone	1	1
Ziprasidone	0	2
Aripiprazole	0	1
Haloperidol	0	1

* Each case may report more than one

Table 3.1.5.1. Descriptive Characteristics of FAERS Cases with PT *Off label use* for Pimavanserin, Received by FDA through March 4, 2018 (N=47)		
	PD, NOS (n=12)	**Non-PD (n=35)**

† Include mania without psychotic symptoms (1), muscle weakness (1), torticollis (1), chronic myeloid leukemia (1), and disturbances of salivary secretion (1)
‡ For the purposes of this review, the following outcomes qualify as serious: death, life-threatening, hospitalization (initial or prolonged), disability, congenital anomaly, required intervention and other serious important medical events.
§ Death cases overlap with cases from **Section 3.1.2**
Definitions: COPD=Chronic obstructive pulmonary disease; MI=Myocardial infarction; NOS=Not otherwise specified

The most common reported off-label reasons for use were dementia (with or without PD) and general psychotic/mental disorder. Most patients were male in the PD, NOS category, but similar between male and female in the non-PD category. The patients' age ranges were similar between non-PD use and PD, NOS use. Most of the cases reported use of concomitant medications including antipsychotics. Among 13 cases that reported concomitant antipsychotic use, eight cases reported use of quetiapine. Twenty-three cases [PD, NOS (4) and non-PD (19)] reported death; however, the majority of the cases did not provide causes of deaths or other clinical details to assess drug-event causality. See **Section 3.1.2** for more details on all death cases in this case series.

3.1.6. Patients < 65 Years of Age

The FAERS search retrieved 96 reports with a serious outcome for patients with <65 years of age. See **Appendix B Table 8.2.5** for the FAERS search strategy for these cases. After accounting for duplicates (3), 93 cases were included in this section. Note: In an effort to provide the full description of cases with a serious outcome for patients < 65 years of age, overlapping FAERS cases from other sections of this review were not excluded. See **Appendix G** for a line listing of these 93 cases.

Table 3.1.6.1. Descriptive Characteristics of FAERS Cases of Patients < 65 Years of Age for Pimavanserin, Received by FDA through March 4, 2018 (N=93)	
Sex	
Male	60
Female	33
Age (years)	
17 - <30	1
30 - <40	2
40 - <50	3
50 - <60	29
60 - <65	58
Reasons for Use	
PDP	55
PD, NOS	26

Table 3.1.6.1. Descriptive Characteristics of FAERS Cases of Patients < 65 Years of Age for Pimavanserin, Received by FDA through March 4, 2018 **(N=93)**	
PD with dementia	1
Dementia	2
Psychotic disorder, NOS	4
Others*	2
Not reported	3
Serious Outcomes[†‡]	(n=93)
Death[§]	27
Hospitalized	51
Disability	1
Other Serious	29
Causes of Death[§]	(n=27)
Not reported	18
PD	3
COPD	1
MI	1
NMS	1
Pneumonia	1
Postoperative complication	1
PE	1
Concomitant medications	
Reported	56
Not reported	37
Concomitant antipsychotics[†]	(n=22)
Quetiapine	18
Haloperidol	3
Clozapine	2
Olanzapine	1
Risperidone	1

*Include drug-drug interaction study (1), and torticollis (1)

[†] Each case may report more than one

[‡] For the purposes of this review, the following outcomes qualify as serious: death, life-threatening, hospitalization (initial or prolonged), disability, congenital anomaly, required intervention and other serious important medical events.

[§] Death cases overlap with cases from **Sections 3.1.2 and 3.1.3**.

Definitions: COPD=Chronic obstructive pulmonary disease; MI=Myocardial infarction; NMS=Neuroleptic Malignant Syndrome; NOS=Not otherwise specified; PD=Parkinson's disease; PDP=Parkinson's disease psychosis; PE=Pulmonary embolism

The majority of patients were male, with an age range from 50 to <65 years. Most cases reported the reason for use as PDP, and reported concomitant medication use. Among 22 cases that reported concomitant antipsychotics use, 18 cases reported use of quetiapine. Of 27 cases that reported death, 26 cases reported patients age ranged between 50 and <65 years. The remaining one fatal case reported a 46-year-old patient with PD developed fever and "shakes,"

then died from "complication of illness." The majority of fatal cases did not provide the cause of death or other clinical details to assess drug-event causality. See **Sections 3.1.2** and 3.1.3 for more details on all death cases in this case series.

For five non-fatal cases reporting patients <50 years of age, four cases reported the reason for use including PD, NOS (2), PDP (1), and psychotic disorder, NOS (1). These cases reported involuntary movements of face and jaw, paranoia and hallucination, peripheral swelling and bloating, and aggression. The time-to-onset of AEs ranged from the same day to two months after starting pimavanserin. Pimavanserin was discontinued in these cases, and one case reported resolution of peripheral swelling and bloating. The other cases did not report whether the AEs resolved after pimavanserin discontinuation. The remaining one non-fatal case of a patient <50 years of age reported receiving pimavanserin during a drug-drug interaction study with rifampin. Eighteen days after the second dose of pimavanserin (four days after the last dose of rifampin), the patient developed confusional state and was hospitalized for evaluation of new onset psychosis.

3.2. DRUG UTILIZATION

To provide context for the AE reports submitted to the FAERS database, U.S. drug utilization patterns for pimavanserin were assessed using the Sponsor-provided data from June 2016 through March 2018.

3.2.1 Number of Tablets[34]

Table 3.2.1.1 below displays the total number of tablets distributed for Nuplazid in the U.S., stratified by channel, from June 2016 through March 2018. During this time, approximately (b) (4) tablets were distributed with nearly (b) (4)% ((b) (4) tablets) going to specialty pharmacies, followed by (b) (4)% (b) (4) tablets) to specialty distributors.

Table 3.2.1.1 Total Number of Tablets Distributed for Nuplazid, Stratified by Channel in the U.S., from June 2016 Through March 2018, Cumulative

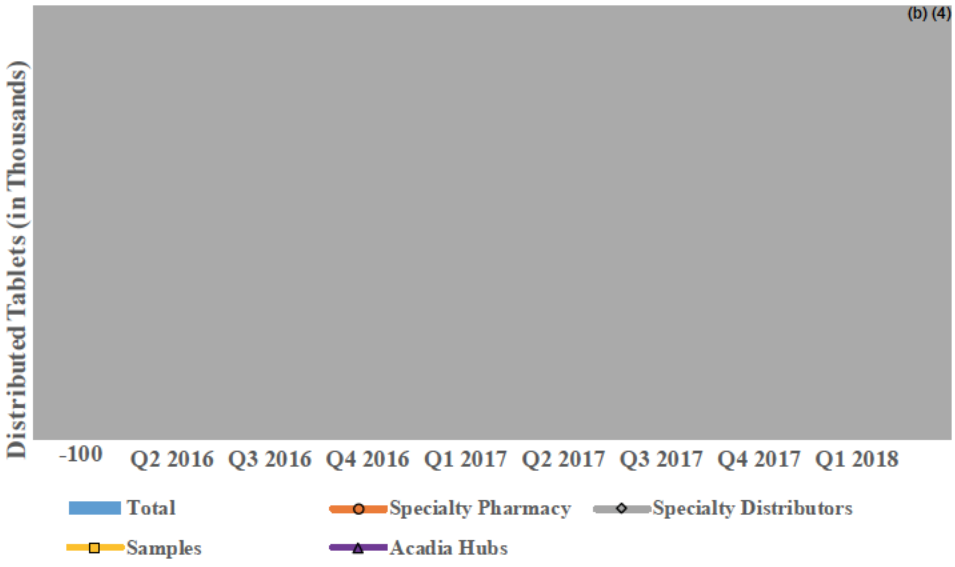
NUPLAZID Tablet Volume by Channel	Tablets	% of Total Volume
Total	(b) (4)	100%
Specialty Pharmacy (SP)[1]		(b) (4)%
Specialty Distributors (SD)[2]		%
Samples[3]		%
ACADIA HUB[4]		%

[1] Specialty Pharmacy (SP) is all mail-order. Four SPs are currently used: CVS, ACS, Walgreens, Accredo.
[2] Specialty Distributor (SD) volume includes tablets shipped from SDs to Group Purchasing Organization (GPO) member pharmacies that service Long Term Care (LTC) and non-GPO member pharmacies that service LTC, Tricare, Veteran Affairs (VA) Hospital, and Kaiser. Four SDs are currently used: McKesson, AmerisourceBergen, Cardinal, HD Smith.
[3] Sample volume represents volume of samples provided to physician's offices, not volume dispensed to patients.
[4] ACADIA HUB volume includes tablets shipped to patients through Free Trial or Patient Assistance Programs (PAPs).

Figure 3.2.1.1 shows the number of tablets distributed for Nuplazid in the U.S., stratified by channel, from Q2 2016 through Q1 2018. Specialty pharmacies accounted for approximatel (b) (4)% ((b) (4) tablets) of total tablets in the second quarter of 2016, increasing to (b) (4)% (b) (4) ablets)

in the first quarter of 2018. Tablets distributed by specialty distributors accounted fo (b) (4) ((b) (4) tablets) of total tablets in the second quarter of 2016, increasing to (b) (4) % (b) (4) tablets) in the first quarter of 2018.

Figure 3.2.1.1 Total Number of Tablets Distributed for Nuplazid in the U.S., Stratified by Channel, from Q2 2016 Through Q1 2018



3.2.2 Number of Patients[34]

Table 3.2.2.1 and **Table 8.8.1** in **Appendix H** displays the total number of unique patients in the U.S. who received a prescription for Nuplazid, from June 2016 through March 2018, cumulative and quarterly, respectively. For the cumulative time, approximately (b) (4) patients received a prescription for Nuplazid. Of the total (b) (4) patients, patients aged 70-79 years accounted for nearly (b) (4)% of total patients (b) (4) patients), followed by patients aged 80 years and older who accounted for (b) (4)% of total patients (b) (4) patients). Similar proportions of use were observed in the quarterly patient data shown in **Appendix H**.

Table 3.2.2.1 Total Number of Unique Patients Who Received a Prescription for Nuplazid, Stratified by Age Groups and Pharmacy Setting of Care in the U.S., from June 2016 Through March 2018, Cumulative

	June 2016 Through March 2018	
	Patient (N)	Share (%)
Total NUPLAZID[1]	(b) (4)	100%
0-9 years		(b) (4)
10-19 years		
20-39 years		
40-59 years		
60-69 years		
70-79 years		
80+ years		
18-45 years*		
46-65 years*		
66-88 years*		
89+ years*		
Unknown Age[2]		
Total NUPLAZID[1]		100%
Mail-order/Specialty		(b) (4)
ACADIA HUB[3]		
Long-term care[4]	Patient Count Not Available	
Outpatient-retail	Not Applicable	

[1] Includes all unique patients who received Nuplazid from specialty pharmacy (SP) or through free trial or patient assistance programs (PAP)
[2] Unknown age represents known unique patients who were shipped Nuplazid through free trial or PAPs but were not serviced by a SP.
[3] Acadia Hub includes unique patients who received Nuplazid through free trial or PAPs but never received Nuplazid from SP, to avoid double counting.
[4] Long-term care (LTC) patients obtain Nuplazid from LTC pharmacies.
* Patient year of birth were not available for the unique patients listed under these age groupings.

3.3. Other Data Sources

3.3.1. PADER

During the reporting period October 29, 2017 to January 28, 2018, the Sponsor received 1,509 reports including 206 fatal reports. Forty-two reports provided the causes of death and the most common causes reported were PD/dementia followed by pneumonia, cardiac related/sudden death, CVA, respiratory failure/COPD, and MI. The Sponsor concluded that the review of fatal reports reflected common morbidities and end of life events in this population, and there was no consistent pattern.

The Sponsor stated that because of their distribution model, there is frequent contact with outpatients by the Sponsor's reimbursement hub and specialty pharmacies, and these frequent

contacts account for the main source of reported AEs. They also calculated a "mortality rate" for the reporting period based on shipments supplied by specialty pharmacies to unique patients.

Reviewer's Comment:
As the Sponsor described, frequent contact with consumers will likely stimulate postmarketing AE reports. Due to lack of clinical details provided in these reports and several underlying risk factors for death in this patient population with PDP, we are not able to determine drug-event causality. See ***Sections 2.3.3*** *and* ***3.3.3*** *for further details on the Sponsor's "mortality rate."*

3.3.2. Thorough QT Study

Design: This was a double-blind, placebo-controlled and positive-controlled (moxifloxacin), 4-arm, multiple-dose parallel design evaluation of QT/QTc interval effects of pimavanserin 20 mg and 80 mg doses once daily in 252 healthy adult subjects after 20 consecutive days of dosing. Study drug was administered for up to 20 days. The four treatment groups included pimavanserin 20 mg (clinical dose), pimavanserin 80 mg (supratherapeutic dose), placebo plus moxifloxacin 400 mg (moxifloxacin on Day 20 only), and placebo. The study included a screening period of up to 30 days that included two days of baseline assessments (Days -2 and -1), a 20-day double-blind treatment period, a final study visit (Day 21) or early termination, pharmacokinetic (PK) sample visits on Days 21 through 24, and a follow-up telephone visit on Day 35 (±2 days). On Day 1, subjects were randomized to receive pimavanserin 20 mg, pimavanserin 80 mg, placebo/moxifloxacin 400 mg, or placebo daily for 20 days. Subjects randomized to the placebo/moxifloxacin group received placebo for Days 1 through 20 plus moxifloxacin 400 mg on Day 20 only.

The Sponsor provided an acceptable justification for the doses selected. The worst-case scenario is illustrated by cytochrome P450 enzyme (CYP) 3A4/5 inhibition with ketoconazole where exposure to pimavanserin increased 1.5-fold for the peak serum concentration (Cmax) from 17.1 to 25.1 ng/mL, and 3-fold for the area under the concentration curve (AUC_{0-24}) from 1224 to 3415 ng·h/mL in Study ACP-103-023. These increases are well-covered by available safety and associated exposure data in humans where single doses of up to 300 mg and multiple doses of up to 150 mg for 14 days have resulted in Cmax values of up to 152 ng/mL (300 mg single dose) and 248 ng/mL (150 mg for 14 days) and corresponding AUCs of up to 10,798 and 4,680 ng·h/mL. At doses ≥100 mg, AEs of dizziness, somnolence, lethargy, nausea, vomiting, dyspepsia, epistaxis, back pain and fatigue have been reported with pimavanserin at rates at least twice those for placebo.

The supratherapeutic dose of 80 mg pimavanserin tested in the TQT study also encompasses the exposures seen when pimavanserin 40 mg was coadministered with ketoconazole. The 80-mg dose was associated with Cmax values of 49.43 and 205.92 ng/mL and AUC values of 860.3 and 3817.1 ng·h/mL at Day 1 and Day 20, respectively. The TQT study also tested pimavanserin 20 mg, moxifloxacin, and placebo and across the four dose groups, the most common treatment-emergent adverse event (TEAE) across treatment groups was headache (13.3%, pimavanserin 20 mg; 22.2%, pimavanserin 80 mg; 22.0%, placebo/moxifloxacin; 19.7%, placebo). Events that occurred in >5% of subjects included headache in the pimavanserin 20 mg, headache, dizziness (15.3%), nausea (12.5%), and rash (5.6%) in the pimavanserin 80 mg group, headache,

pharyngolaryngeal pain and diarrhea (5.1%) in the placebo/moxifloxacin group, and nausea (6.6%) in the placebo group. Events that occurred in ≥10.0% of pimavanserin 80 mg-treated subjects and twice the incidence of pimavanserin 20 mg-treated subjects included nausea (12.5% vs. 1.7%) and dizziness (15.3% vs. 3.3%).

Reviewer's Comment: The studied doses are acceptable. The study result is positive. Although the therapeutic dose (40 mg daily) was not directly studied in this TQT study, the studied exposure range covered the clinically relevant exposure.

Overall summary of findings: **Table 3.3.2.1** summarizes the findings below. Using QTcI correction, a marginal QTc prolongation effect of pimavanserin at the 80-mg dose once daily after 20 consecutive days of dosing was detected in this TQT study. The largest upper bound of the two-sided 90% CI for the mean difference between pimavanserin 80 mg and placebo is 16.6 ms at 6 hours postdose on Day 20. The largest lower bound of the two-sided 90% CI for the ΔΔQTcI for moxifloxacin was greater than 5 ms, and the moxifloxacin profile over time is adequately demonstrated in **Table 3.3.2.1.**, indicating that assay sensitivity was established. The therapeutic dose of 40 mg once daily for pimavanserin is not directly studied in this TQT trial. Based on the linear PK of pimavanserin, the 80-mg dose studied in this study is expected to provide a 2-fold margin over the therapeutic exposure. CYP3A4/5 inhibitor ketoconazole increases pimavanserin Cmax 50% and triples AUC in the single-dose study. The effect of hepatic impairment and renal impairment on pimavanserin PK are unknown. Based on the concentration-QTc relationship, a marginal QTc prolongation is expected at the therapeutic concentration.

Table 3.3.2.1. The Point Estimates and the 90% CIs Corresponding to the Largest Upper Bounds for Pimavanserin (20 mg and 80 mg) and the Largest Lower Bound for Moxifloxacin (FDA Analysis)

Treatment	Time (hour)	ΔΔQTcI (ms)	90% CI (ms)
Pimavanserin 20 mg	1	4.4	(1.6, 7.2)
Pimavanserin 80 mg	6	13.5	(10.3, 16.6)
Moxifloxacin 400 mg*	4	11.2	(8.2, 14.2)

* Multiple endpoint adjustment was not applied. The largest lower bound after Bonferroni adjustment for 4 timepoints is 7.1 ms.

The results of the TQT study informed decisions about labeling for the following sections: Warnings and Precautions, Drug Interactions, and Pharmacodynamics. The QT-IRT provided recommendations for labeling language.

3.3.3. Sponsor's IR Response[23-25]

The Sponsor's response included an analysis of all fatal pimavanserin AE reports received by the Sponsor from April 29, 2016 (FDA approval date) through February 28, 2018. During this period, 885 fatal AE reports were received by the Sponsor, and were included in their analysis.

An estimated (b) (4) patients were exposed to pimavanserin since the commercial launch of the drug (May 31, 2016) through February 28, 2018, with an estimated (b) (4) patient-years of exposure.

Overall, the Sponsor was unable to identify a causal relationship between pimavanserin and any specific AE that resulted in death. Following are highlights of the Sponsor's analysis and conclusions:

- The majority of the distribution of pimavanserin to patients is through specialty pharmacies (b) (4)%). Approximately (b) (4)% of AE reports received by the Sponsor are considered solicited reports from frequent contacts with consumers by the Sponsor's reimbursement hub and specialty pharmacy network. The Sponsor claims that this distribution mechanism for pimavanserin results in a larger number of AE reports to the Sponsor "than would be expected via routine voluntary spontaneous [non-solicited] reporting."

DPV-I Reviewer's comment:
A sponsor that has more frequent contact with consumers via reimbursement hubs, patient assistance programs, specialty pharmacies, or any other patient support programs is likely to stimulate more AE reports than a sponsor that does not have frequent contact with consumers via these mechanisms. The seemingly large number of death reports observed with pimavanserin may reflect solicited reporting and prescribing to elderly patients with advanced PD who may have multiple risk factors for death.

- The Sponsor used the total of spontaneous and solicited reports of death (n=885) as the numerator, and patient-years of exposure in the U.S. population estimated from distribution data as the denominator (n=6,205 patient-years), to calculate a "mortality rate" of 14.26 deaths per 100 person-years (95% CI: 13.34, 15.23). The Sponsor compared this "mortality rate" with other mortality rates per 100 patient-years derived from different sources:
    - The Sponsor's clinical trials (Phase 2 and 3 double-blind, placebo-controlled studies in PD and Alzheimer's disease; placebo: n=357; pimavanserin: n=510): The Sponsor's table below is reproduced from their response to our IR, received by FDA April 19, 2018. Deaths occurring within 30 days of the last dose of study treatment were included. (The Sponsor also notes that there were no deaths in Phase 1-type studies.)

Table 1 Summary of Deaths: Phase 2/3 PD/PDP/ADP Clinical Studies[1] Completed by End of 2016 (Safety Analysis Set)

Statistics	Placebo	PIM[2]
Total Number of Subjects	357	510
Number of Deaths[3]	5	6
Person-Years (PY) of Exposure[4]	45.8	60.0
Mortality Rate per 100 PY	10.9	10.0
95% CI of Mortality Rate per 100 PY	(3.5, 25.5)	(3.7, 21.8)

Abbreviations: ADP=Alzheimer's disease psychosis; CI=confidence interval; PD=Parkinson's disease; PDP=Parkinson's disease psychosis; PIM=pimavanserin; PY=person-years

1 Study treatment period ≤12 weeks.

2 ACP-103-005, -006, -012, -014, -020, (b) (4) including fixed doses of PIM 8.5 mg (-012, -014), 17 mg (-014), 21 mg (-005), 34 mg (-012, -020, (b) (4)), 85 mg (-005) and flexible-doses of 17-51 mg (-006).

3 Deaths that occurred within 30 days after last study dose date.

4 Total cumulative person-years on study medication.

- Mortality rates for patients with PD taking antipsychotics published in the medical literature: Weintraub et al. studied patients with PD on antipsychotic medications. Their retrospective cohort study in the Veterans Health Administration[19] examined mortality in a cohort of 7,877 medically stable patients with PD with a mean age of 76 years who began antipsychotics, compared to a matched sample of patients with PD not using antipsychotics. Antipsychotics were associated with higher mortality (hazard ratio 2.4, 95% confidence interval 2.1-2.7 compared to non-use). In absolute terms, the mortality with antipsychotic use ranged from 51 per 100 patient years with haloperidol to 12 per 100 patient years with "other" atypical antipsychotics.

The Sponsor also included an abstract from a recently completed observational study utilizing U.S. Medicare data from January 1, 2012 to December 31, 2015. The purpose of the study was to determine the background mortality rates and comorbidities in patients with PD with and without psychosis. The results are provided in **Table 3.3.3.1** below.

Table 3.3.3.1. Mortality Rates in Patients with Parkinson's Disease with and Without Psychosis	
U.S. Medicare Data (January 1, 2012 – December 31, 2015)	Age Standardized Mortality Rates per 100 Person-Year of Follow Up per U.S. Census 2010 (95% CI)
Parkinson's disease	7.31 (7.15-7.47)
Parkinson's disease psychosis	28.18 (27.53-28.8)

Taking all of these data sources together, the Sponsor concludes that patients with PDP "are at higher risk of death, and that postmarketing mortality rates for [pimavanserin] are consistent with what is seen in the general PDP population."

DPV-I Reviewer's Comment:

The "mortality rate" the Sponsor calculated from the postmarketing reporting rate is not useful. We cannot estimate underreporting and control for the number of unreported deaths in patients exposed to pimavanserin, and therefore cannot estimate the accuracy of this "mortality rate." There is insufficient evidence to conclude that postmarketing mortality rates for pimavanserin are consistent with mortality rates in the general PDP population. The Sponsor does provide an abstract describing observational data showing patients with PDP are at higher risk of death compared to PD patients without psychosis. See DEPI-1 Reviewer's Comment below for additional details.

<u>DEPI-I Reviewer's Comment</u>:
The principle question is how closely the Sponsor's reporting rate for fatal AEs (which the Sponsor labels a "mortality rate") approximates the true mortality rate among pimavanserin users. The Sponsor estimated (b) (4) *patient-years of exposure through February 28, 2018 from the total days supply distributed to individual patients by specialty pharmacies (representing* (b) (4) *patient-years) and the total days supply distributed directly to patients as free product (representing* (b) (4) *patient-years). The Sponsor did not include product shipped to an institution or healthcare system that was not designated for specific patients. To the extent that the Sponsor's method of estimating exposed patient-years omits some pimavanserin use, that would reduce the numerator and thus bias the rate upwards. A far more salient concern, however, is under-reporting of deaths; the number of fatal AE reports represents some unknown fraction of the true number of deaths, and the smaller that fraction, the more the rate estimate is biased downward. The Sponsor argues that under-reporting of deaths is apt to be minimal because of the way pimavanserin is distributed, but the actual degree of under-reporting remains unknown.*

The Sponsor classifies reports of death through specialty pharmacies as "solicited" and other reports as "spontaneous." They state in their response to the April 13, 2018 IR that approximately 85% of all pimavanserin AE reports are "solicited." If we apply that percentage to the 885 fatal AE reports, it would suggest that 752 of the fatal reports were solicited and 133 were spontaneous. If one takes 752 solicited reports for the numerator and (b) (4) *patient-years of specialty pharmacy exposure as the denominator, the reporting rate for solicited reports of death is* (b) (4) *per 100 patient-years. This is indeed somewhat higher than the corresponding reporting rate for non-solicited reports (i.e., 133 spontaneous death reports with* (b) (4) *patient-years of non-specialty pharmacy exposure gives a reporting rate of* (b) (4) *per 100 patient-years). However, the difference between the two is likely to be even greater, as the Sponsor states that they did not start classifying solicited reports as such until January 29, 2017; i.e., some portion of the 133 "spontaneous" reports of death were actually from specialty pharmacy use prior to January 29, 2017. Accordingly, there is some support for the Sponsor's assertion that the specialty pharmacy distribution practices generate more reports of deaths, but it is still not possible to make reliable comparisons of those numbers to other data.*

The Sponsor's updated controlled clinical trial mortality data indicate that adding the Alzheimer's disease trial data to the Parkinson's trial data diminishes the numeric imbalance of deaths present in the original NDA submission [4 on pimavanserin (1%) and 1 (0.4%) on placebo in controlled trials][35]. However, from a quantitative standpoint the reassurance provided is limited; while the incidence rate ratio (pimavanserin:placebo) is 0.92, the 95% CI is wide (0.27-3.26)[36]. Additionally, patients with PD may have different tolerance for pimavanserin

from patients with Alzheimer's disease. The Sponsor's May 11, 2018 Sequence 0071 response to an April 13, 2018 IR provided an updated analysis of deaths in placebo-controlled trials, adding in two deaths on pimavanserin that occurred more than 30 days after the last dose, and data from recently completed trial (b) (4) *in Alzheimer's disease. The updated mortality rates per 100 person-years, with 5 deaths on placebo and 8 on pimavanserin, are 9.3 for placebo and 10.8 for pimavanserin (rate ratio 1.2, 95% CI: 0.38-3.9).*

- The most common cause of death reported among the fatal AE reports was death, NOS or unreported cause (n=590; 67%). The top five specified causes of death were advanced or end-stage PD/progression dementia (n=123; 14%), pneumonia/aspiration pneumonia (n=38; 4%), MI (n=19; 2%), cardio-pulmonary/respiratory failure (n=19; 2%), and sepsis (n=15; 2%). Mean age was 78 years (range 46-96). No consistent pattern or trend was identified among the causes of death, except that they were "reflective of the common comorbidities and end of life events common in this population."

DPV-I Reviewer's Comment:
It is typical for postmarketing reports to include limited clinical information on the cause of death. An evaluation of the case report involving the youngest patient in the analysis, a 46-year-old male (FAERS Case# 13880412), did not reveal a causal relationship between pimavanserin and the AE (i.e., causality was unassessable due to lack of information). Of note, the Sponsor reportedly documents follow-up attempts on fatal AE reports. See ***Section 3.1.2*** *for FAERS case summary.*

- The Sponsor conducted an analysis of individual case reports in which the cause of death was reported as one of the following: advanced or end-stage PD/progression of dementia-related (n=82), cardiac-related (n=54), CVA (n=10), pneumonia-related (n=36), cardio-respiratory/respiratory failure-related (n=19), and sepsis-related (n=15) (number of cases per cause of death is different from what is listed in the preceding bullet point because the Sponsor used different definitions for cause of death in their individual case analyses). Case reports across all the above listed causes of death had several limitations. The cases either lacked pertinent information to assess causality, or reported several confounders. Cases often did not include information on concomitant medications or medical history. Cases that did report such information revealed several confounders, such as multiple comorbidities (e.g., cardiovascular disease, diabetes, dementia), as well as concomitant medications (e.g., antipsychotics, antidepressants, donepezil, memantine, antihypertensives, antihyperglycemic drugs). The analysis also examined duration of therapy prior to the event, and did not identify any specific trends. The Sponsor concluded "there is no evidence of a causal relationship with [pimavanserin] and the overall risk/benefit profile for [pimavanserin] remains positive."

DPV-I Reviewer's Comment:
Incomplete reports and lack of a comparison group provide several limitations for assessing causality. After reviewing the postmarketing data included in the Sponsor's IR response, we

were unable to identify evidence of a causal relationship between pimavanserin and a specific pathophysiological process that hastens death.

4. DISCUSSION

Our review did not identify any new or unexpected safety findings with pimavanserin in the postmarketing safety analysis, compared to the safety profile established in the premarketing trials. DPV, DEPI-I and DEPI-II utilized the pimavanserin product labeling, top PTs reported for pimavanserin in FAERS, analysis of select FAERS cases, the Sponsor's PADER, the Sponsor's IR responses, the TQT study results, and relevant published medical literature on PD, PDP, and the use of antipsychotics in PD and dementia to provide information about potential safety risks reported with the use of pimavanserin.

To provide context for the FAERS reports, U.S. drug utilization patterns for pimavanserin were assessed using the Sponsor-provided data from June 2016 through March 2018. The majority of use was in elderly patients with approximately 35-39% of total patients who received Nuplazid prescriptions aged 70-79 years, followed by patients aged 80+ years accounting for approximately 27-30% of patients. In the second quarter of 2016, approximately (b) (4) total tablets were distributed to all settings of care, increasing to (b) (4) tablets in the first quarter of 2018. The number of tablets distributed to specialty pharmacies accounted for approximately (b) (4)% ((b) (4) tablets) of total tablets in the second quarter of 2016, increasing t (b) (4)% ((b) (4) ablets) in the first quarter of 2018.

Pimavanserin is almost exclusively distributed by specialty pharmacies and specialty distributors. Frequent contact with consumers via reimbursement hubs, patient assistance programs, or specialty pharmacies can explain the high number of postmarketing AE reports for pimavanserin. Drug utilization data and FAERS data showed patients aged 70 years or older accounted for the highest proportion of pimavanserin use.

The majority of FAERS cases were solicited by Nuplazid Connect or specialty pharmacies, and these cases often provided insufficient information to assess drug-event causality. Because of limited clinical details and the presence of several underlying patient risk factors, these postmarketing AE reports are challenging to interpret. In addition, FAERS data analysis generally cannot detect a drug-related increase or difference in events with high background rates or known drug-related events (e.g., death, other SAE, and QT effects). Our FAERS cases reported a wide range of time-to-onset of AEs in relation to pimavanserin treatment, and included patients having advanced PD with several underlying risk factors for death such as advanced age, multiple cardiovascular and other comorbidities, and multiple concomitant medications posing serious risks in PD patients, including antipsychotics. Antipsychotic use in elderly patients with dementia or PD increases the risk of all-cause mortality. Furthermore, numerous cases reported concomitant use of pimavanserin and other drugs that can prolong the QT interval, particularly antipsychotics and antidepressants.

Pimavanserin can also cause QT prolongation, and it may increase the risk of life-threatening arrhythmia; thus, it could have contributed to some of the reported cardiovascular SAEs. However, our review of FAERS cases did not capture any cases of TdP, other ventricular

arrhythmias, or any fatalities in the cases of reported QT prolongation. Most cases reporting QT prolongation had limited information, lacked baseline ECGs for comparison, and did not have confirmation of actual QT prolongation. In addition, many cases involved additional risk factors for QT prolongation, including MI, acute ischemia, or use of other QT-prolonging drugs (e.g. quetiapine, olanzapine, clozapine, paliperidone, citalopram, escitalopram, fluoxetine, and antiarrhythmics) or diuretics. It is possible that some of the cases reported as sudden death, cardiac arrest, syncope, and LOC were related to pimavanserin, secondary to QT prolongation; however, we do not have sufficient evidence (i.e., report of QT prolongation associated with these events) at this time to determine a causal relationship.

The DARS review team made several predictions about AEs that might be reported with postmarketing pimavanserin use, based on safety considerations with cyproheptadine, a serotonergic drug with some receptor pharmacology similarities with pimavanserin; however, the drugs do not have fully overlapping pharmacology. The DARS team concluded that pimavanserin could aggravate autonomic dysfunction (primarily BP lability), falls, and insomnia in some patients with PDP. They also noted that patients with PD are known to have these comorbidities secondary to their underlying disease process. For example, patients with PD commonly suffer from autonomic instability, including orthostatic hypotension, and they have multiple risk factors for falls. The pimavanserin controlled trials did not demonstrate increased rates of BP changes or abnormalities, falls, or insomnia. Postmarketing cases included reports for all of these AEs. However, we could not establish a causal role for pimavanserin in these cases, because all of these AEs occur commonly in patients with PDP as comorbid conditions secondary to PD pathophysiology or treatments for PD. In addition, the cases pertaining to BP abnormalities did not include clinically confirmed, objective vital sign data (pretreatment or on-treatment), there were multiple risk factors for BP changes, and there were few clear temporal relationships between AEs and pimavanserin. Only one case of syncope also reported low BP. Some of the most commonly reported postmarketing SAEs with pimavanserin included falls, confusional state, and gait abnormalities. Furthermore, the pimavanserin controlled trials demonstrated increased rates of gait disturbance and confusional states (compared to placebo), both of which can increase the risk of falls. Gait disturbance and confusional state are labeled in the Adverse Reactions section. However, given the limitations of the FAERS data described above, it was not possible to reach conclusions about a causal role for pimavanserin in these SAEs. There were postmarketing reports of insomnia, but we could not reach conclusions about causality for similar reasons. PDP patients commonly have sleep disturbances, and the cases were not conclusive.

In the controlled trials, pimavanserin was associated with an increase in all-cause mortality and all-cause SAEs, compared to placebo. However, there was no identified unifying mechanisms to explain the findings. Thus, in addition to its QT prolongation effects, it is possible that pimavanserin had a causal role in some of the fatalities and other SAEs during postmarketing use. However, there were no unexpected causes of deaths or other SAEs in the postmarketing cases, and there was no unifying biologic mechanism to explain the fatal or SAEs, consistent with the findings in the premarketing program.

The Sponsor's updated analysis of deaths in placebo-controlled trials (5 deaths with placebo and 8 with pimavanserin) found mortality rates per 100 person-years of 9.3 for placebo and 10.8 for

pimavanserin (rate ratio 1.2, 95% confidence limit 0.38-3.9), which is difficult to interpret because the estimate is imprecise. The Sponsor's "mortality rate" calculated from the postmarketing fatal event reporting rate must also be interpreted cautiously because the degree of underreporting of deaths is unknown, even if one allows that the distribution system for pimavanserin encourages reporting. Accordingly, this postmarketing "mortality rate" cannot be reliably compared to other sources of data, given the unknown amount of underreporting.

Although there were no new or unexpected safety findings, many patients with PDP in the FAERS cases were being treated concomitantly with pimavanserin and other QT interval-prolonging drugs, further increasing the risk of QT prolongation and life-threatening arrhythmias. Numerous patients were treated concomitantly with antipsychotics that can prolong the QT interval and have QT warnings, including: quetiapine, clozapine, asenapine, paliperidone, and iloperidone. Several patients were treated with the antidepressant, citalopram, which can cause QT prolongation. These QT-prolonging drugs are currently not discussed in pimavanserin labeling. It may be worthwhile to further emphasize these risks in the labeling along with a Drug Safety Communication.

5. CONCLUSIONS

Although we did not identify any new or unexpected safety findings with pimavanserin in the postmarketing analysis at this time, it may be worthwhile to further emphasize in labeling the risks of concomitantly administering pimavanserin with other QT interval-prolonging drugs. It may also be useful to consider a Drug Safety Communication discussing these risks.

6. RECOMMENDATIONS

Based on this review, OPE recommends the following:

- Revise the Warnings and Precautions (QT Interval Prolongation), and Drug Interactions sections to emphasize the increased risk of QT prolongation and life-threatening cardiovascular events when treating patients concomitantly with pimavanserin and other drugs that can prolong the QT interval. We recommend listing specific antipsychotics which are known to cause QT prolongation and have QT warnings (quetiapine, clozapine, asenapine, paliperidone, and iloperidone), as well as the antidepressant, citalopram, known to cause QT prolongation. All of these drugs were used concomitantly in the pimavanserin FAERS cases.
- Consider issuing a Drug Safety Communication to discuss these serious risks.
- Consider developing a Medication Guide to educate patients and caregivers about these risks.

DPV will continue to monitor all AEs for pimavanserin, with focus on trends in the death reports, AEs related to autonomic instability or CNS toxicity, and serious cardiovascular AEs.

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8. APPENDICES

8.1. APPENDIX A. FDA ADVERSE EVENT REPORTING SYSTEM (FAERS)

FDA Adverse Event Reporting System (FAERS)

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products. The informatic structure of the database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. Adverse events and medication errors are coded to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. The suspect products are coded to valid tradenames or active ingredients in the FAERS Product Dictionary (FPD).

FAERS data have limitations. First, there is no certainty that the reported event was actually due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event. Further, FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether or not an event will be reported, such as the time a product has been marketed and publicity about an event. Therefore, FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population.

8.2. APPENDIX B. FURTHER DETAILS ON FAERS SEARCH STRATEGIES

Table 8.2.1. FAERS Search Strategy* - Death	
Date of Search	March 8, 2018
Time Period of Search	All reports through March 4, 2018
Search Type	FBIS Quick Query
Product Terms	Product Active Ingredient: Pimavanserin, Pimavanserin tartrate
MedDRA Search Terms (Version 20.1)	All
Outcome	Death
* See **Appendix A** for a description of the FAERS database. Definition: FBIS=FDA Business Intelligence Solution; MedDRA=Medical Dictionary for Regulatory Activities	

Table 8.2.2. FAERS Search Strategy* - Torsades de Pointes/QT prolongation	
Date of Search	March 26, 2018
Time Period of Search	All reports through March 4, 2018
Search Type	FBIS Quick Query
Product Terms	Product Active Ingredient: Pimavanserin, Pimavanserin tartrate
MedDRA Search Terms (Version 20.1)	Torsades de Pointes/QT prolongation SMQ (broad)
* See **Appendix A** for a description of the FAERS database. Definitions: FBIS=FDA Business Intelligence Solution; MedDRA=Medical Dictionary for Regulatory Activities; SMQ=Standardised MedDRA Queries	

Table 8.2.3. FAERS Search Strategy* - Other Events of Interest	
Date of Search	**March X, 2018**
Time Period of Search	All reports through March 4, 2018
Search Type	FBIS Quick Query
Product Terms	Product Active Ingredient: Pimavanserin, Pimavanserin tartrate
MedDRA Search Terms (Version 20.1)	PTs: *Seizure, Cerebrovascular accident, Myocardial infarction, Deep vein thrombosis*
Outcome	Serious[†]
* See **Appendix A** for a description of the FAERS database. [†] For the purposes of this review, the following outcomes qualify as serious: death, life-threatening, hospitalization (initial or prolonged), disability, congenital anomaly, required intervention and other serious important medical events. Definitions: FBIS=FDA Business Intelligence Solution; MedDRA=Medical Dictionary for Regulatory Activities; PT=Preferred Term	

Table 8.2.4. FAERS Search Strategy* - Off-Label Use	
Date of Search	March 8, 2018
Time Period of Search	All reports through March 4, 2018
Search Type	FBIS Quick Query
Product Terms	Product Active Ingredient: Pimavanserin, Pimavanserin tartrate
MedDRA Search Terms (Version 20.1)	PT *Off label use*
Outcome	Serious†

***** See **Appendix A** for a description of the FAERS database.
† For the purposes of this review, the following outcomes qualify as serious: death, life-threatening, hospitalization (initial or prolonged), disability, congenital anomaly, required intervention and other serious important medical events.
Definitions: FBIS=FDA Business Intelligence Solution; MedDRA=Medical Dictionary for Regulatory Activities; PT=Preferred Term

Table 8.2.5. FAERS Search Strategy* - Patients with <65 Years of Age	
Date of Search	March 8, 2018
Time Period of Search	All reports through March 4, 2018
Search Type	FBIS Quick Query
Product Terms	Product Active Ingredient: Pimavanserin, Pimavanserin tartrate
MedDRA Search Terms (Version 20.1)	**All**
Outcome	Serious†
Age	To 64.99999 years

***** See **Appendix A** for a description of the FAERS database.
† For the purposes of this review, the following outcomes qualify as serious: death, life-threatening, hospitalization (initial or prolonged), disability, congenital anomaly, required intervention and other serious important medical events.
Definition: FBIS=FDA Business Intelligence Solution; MedDRA=Medical Dictionary for Regulatory Activities

8.3. APPENDIX C. FAERS LINE LISTING OF FATAL CASE SERIES

FAERS Line Listing of Fatal Case Series for Pimavanserin, Received by FDA through March 4, 2018 (N=893)									
	Initial FDA received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
1.	12/17/2012	8974274	1		Direct	66	Female	USA	DE
2.	7/1/2016	12520599	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000039	Expedited	67.56	Female	USA	DE,HO
3.	7/19/2016	12568812	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000130	Expedited	86.62	Male	USA	DE
4.	7/21/2016	12578162	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000019	Expedited	81.33333	Male	USA	DE,HO
5.	7/22/2016	12581873	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000175	Expedited	78.66393	Male	USA	DE
6.	7/27/2016	12595990	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000184	Expedited	89	Male	USA	DE
7.	7/29/2016	12608799	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000249	Expedited	84.54	Male	USA	DE
8.	8/2/2016	12615221	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000237	Expedited	81	Male	USA	DE,HO
9.	8/8/2016	12628188	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000272	Expedited	82.27	Female	USA	DE
10.	8/12/2016	12647160	5	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000274	Expedited	92	Male	USA	DE,HO
11.	8/12/2016	12647166	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000309	Expedited	68.42163	Male	USA	DE
12.	8/17/2016	12658748	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000345	Expedited	77	Male	USA	DE,HO,OT
13.	8/18/2016	12663573	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000006	Expedited	69	Female	USA	DE,OT
14.	8/18/2016	12663612	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000069	Expedited	72	Male	USA	DE
15.	8/18/2016	12663640	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000127	Expedited	69	Male	USA	DE
16.	8/18/2016	12663739	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000153	Expedited	81	Male	USA	DE
17.	8/18/2016	12663781	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000176	Expedited	74	Female	USA	DE
18.	8/18/2016	12663808	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000052	Expedited	85	Male	USA	DE,OT
19.	8/18/2016	12663577	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000060	Expedited	NR	Male	USA	DE
20.	8/18/2016	12663617	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000062	Expedited	83.15948	Female	USA	DE
21.	8/18/2016	12663661	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000106	Expedited	88	Female	USA	DE,HO
22.	8/18/2016	12663691	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000182	Expedited	73.16	Male	USA	DE,OT
23.	8/18/2016	12663699	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000197	Expedited	80	Male	USA	DE
24.	8/18/2016	12663730	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000231	Expedited	87.14579	Male	USA	DE
25.	8/18/2016	12663744	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000232	Expedited	74	Male	USA	DE,HO
26.	8/18/2016	12663751	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000165	Expedited	54.68036	Male	USA	DE
27.	8/18/2016	12663754	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000061	Expedited	85.50034	Female	USA	DE,HO
28.	8/18/2016	12663789	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000190	Expedited	87	Female	USA	DE
29.	8/18/2016	12663799	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000234	Expedited	78.65845	Male	USA	DE
30.	8/22/2016	12670589	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000362	Expedited	72	Male	USA	DE,HO,OT
31.	8/22/2016	12670588	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000379	Expedited	75.72	Female	USA	DE,HO
32.	8/24/2016	12678985	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000363	Expedited	83.19	Female	USA	DE
33.	8/25/2016	12682663	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000389	Expedited	81.25	Male	USA	DE,HO
34.	8/26/2016	12689689	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000432	Expedited	75.2334	Male	USA	DE
35.	8/31/2016	12703541	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000487	Expedited	67.19781	Male	USA	DE,HO
36.	8/31/2016	12703542	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000509	Expedited	78.49692	Male	USA	DE,HO
37.	8/31/2016	12703552	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000301	Expedited	74.4449	Female	USA	DE

FAERS Line Listing of Fatal Case Series for Pimavanserin, Received by FDA through March 4, 2018 (N=893)									
	Initial FDA received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
38.	8/31/2016	12703553	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000511	Expedited	66	Male	USA	DE
39.	9/1/2016	12707415	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000460	Expedited	79	Male	USA	DE
40.	9/5/2016	12713936	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000510	Expedited	76.74196	Male	USA	DE,HO
41.	9/5/2016	12714032	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000544	Expedited	75.72348	Male	USA	DE
42.	9/7/2016	12720849	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000559	Expedited	NR	Male	USA	DE,HO,OT
43.	9/8/2016	12723312	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000570	Expedited	68.49829	Male	USA	DE
44.	9/12/2016	12731384	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000605	Expedited	82.56	Male	USA	DE
45.	9/12/2016	12731385	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000591	Expedited	85.04312	Male	USA	DE
46.	9/14/2016	12740796	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000621	Expedited	90.47502	Female	USA	DE
47.	9/15/2016	12744948	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000637	Expedited	70.51335	Female	USA	DE
48.	9/15/2016	12744949	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000616	Expedited	67.93429	Female	USA	DE
49.	9/16/2016	12753101	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000643	Expedited	80	Male	USA	DE
50.	9/21/2016	12764989	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000694	Expedited	82.67488	Female	USA	DE
51.	9/23/2016	12773809	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000702	Expedited	75.46612	Male	USA	DE,HO
52.	9/23/2016	12773812	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000719	Expedited	90.84463	Male	USA	DE
53.	9/26/2016	12778471	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000715	Expedited	84.61	Female	USA	DE,HO
54.	9/29/2016	12791635	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000748	Expedited	68.23819	Male	USA	DE
55.	9/30/2016	12798353	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000747	Expedited	82.89665	Male	USA	DE,HO,OT
56.	9/30/2016	12798361	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000761	Expedited	89.83	Female	USA	DE,HO
57.	10/3/2016	12802572	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000791	Expedited	60.72005	Female	USA	DE
58.	10/5/2016	12810616	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000737	Expedited	80	Female	USA	DE,OT
59.	10/5/2016	12811379	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000815	Expedited	79	Male	USA	DE
60.	10/5/2016	12811380	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000857	Expedited	NR	Female	USA	DE
61.	10/5/2016	12811405	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000739	Expedited	69	Female	USA	DE
62.	10/7/2016	12824461	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000836	Expedited	80.87064	Male	USA	DE,HO
63.	10/12/2016	12838467	5	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000887	Expedited	75	Female	USA	DE,HO,OT
64.	10/12/2016	12838476	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000870	Expedited	73.32512	Female	USA	DE
65.	10/13/2016	12842326	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000912	Expedited	79	Female	USA	DE,OT
66.	10/14/2016	12847173	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000907	Expedited	76.72827	Female	USA	DE,HO
67.	10/14/2016	12847177	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000895	Expedited	85	Male	USA	DE
68.	10/14/2016	12847513	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000925	Expedited	79	Male	USA	DE
69.	10/17/2016	12853037	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000879	Expedited	89	Female	USA	DE
70.	10/18/2016	12857421	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000928	Expedited	63	Male	USA	DE
71.	10/18/2016	12857424	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000949	Expedited	74	Male	USA	DE
72.	10/19/2016	12861993	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000932	Expedited	72.14784	Male	USA	DE,HO
73.	10/21/2016	12879829	1		Direct	77.79	Male	USA	DE
74.	10/24/2016	12876524	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000986	Expedited	62	Male	USA	DE,HO
75.	10/24/2016	12876525	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000973	Expedited	82	Female	USA	DE
76.	10/24/2016	12876534	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000993	Expedited	88.62	Female	USA	DE
77.	10/24/2016	12884448	1		Direct	62.83	Male	USA	DE

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	Initial FDA received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
78.	10/25/2016	12880084	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001016	Expedited	84.54757	Male	USA	DE
79.	10/26/2016	12884840	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001029	Expedited	83	Male	USA	DE,HO
80.	10/28/2016	12891731	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001026	Expedited	93.67283	Female	USA	DE
81.	10/28/2016	12891732	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001048	Expedited	81.10609	Male	USA	DE,HO
82.	10/28/2016	12891737	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001040	Expedited	69.45	Female	USA	DE,HO
83.	10/31/2016	12895802	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001053	Expedited	77.78782	Male	USA	DE
84.	11/1/2016	12898920	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001078	Expedited	96.71184	Male	USA	DE
85.	11/2/2016	12902488	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000315	Expedited	90	Male	USA	DE,HO,OT
86.	11/2/2016	12903828	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001050	Expedited	84.93087	Male	USA	DE
87.	11/3/2016	12906168	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001081	Expedited	78.53799	Male	USA	DE
88.	11/4/2016	12911963	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001104	Expedited	70.07529	Male	USA	DE,OT
89.	11/4/2016	12911966	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000589	Expedited	74.90212	Male	USA	DE,HO
90.	11/4/2016	12912036	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001125	Expedited	83.96441	Male	USA	DE
91.	11/4/2016	12912053	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001127	Expedited	69	Male	USA	DE
92.	11/8/2016	12919086	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001067	Expedited	63	Male	USA	DE
93.	11/9/2016	12923694	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001144	Expedited	75	Male	USA	DE,HO
94.	11/10/2016	12929341	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001169	Expedited	66	Male	USA	DE
95.	11/10/2016	12929342	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001197	Expedited	68.49281	Female	USA	DE
96.	11/14/2016	12937890	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000664	Expedited	71	Male	USA	DE
97.	11/14/2016	12938131	8	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000876	Expedited	86	Male	USA	DE
98.	11/14/2016	12938136	6	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000888	Expedited	79	Male	USA	DE,HO
99.	11/14/2016	12938332	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000676	Expedited	75	Male	USA	DE
100.	11/14/2016	12939253	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001074	Expedited	75	Male	USA	DE
101.	11/14/2016	12936610	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001178	Expedited	91.90691	Female	USA	DE
102.	11/14/2016	12936611	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001189	Expedited	72.33949	Male	USA	DE
103.	11/14/2016	12938001	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000744	Expedited	81	Male	USA	DE,OT
104.	11/14/2016	12938072	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000834	Expedited	88.31211	Female	USA	DE
105.	11/14/2016	12938080	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000795	Expedited	80	Male	USA	DE
106.	11/14/2016	12938234	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000961	Expedited	78	Female	USA	DE
107.	11/14/2016	12938260	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001011	Expedited	77	Female	USA	DE,HO
108.	11/14/2016	12938264	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001024	Expedited	80	Female	USA	DE
109.	11/14/2016	12938467	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000376	Expedited	71.61944	Male	USA	DE
110.	11/14/2016	12938470	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000375	Expedited	81.24025	Male	USA	DE
111.	11/14/2016	12938552	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000422	Expedited	61.10335	Male	USA	DE
112.	11/14/2016	12938789	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000503	Expedited	87.05	Male	USA	DE,HO
113.	11/14/2016	12939184	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000330	Expedited	78	Female	USA	DE
114.	11/14/2016	12939337	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001090	Expedited	75.04449	Female	USA	DE
115.	11/14/2016	12939345	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001072	Expedited	67	Male	USA	DE
116.	11/15/2016	12939796	6	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001202	Expedited	75	Male	USA	DE,HO
117.	11/15/2016	12939809	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001198	Expedited	66.29706	Male	USA	DE

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	Initial FDA received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
118.	11/16/2016	12946723	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001196	Expedited	80	Male	USA	DE,OT
119.	11/16/2016	12946727	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001210	Expedited	78.69952	Male	USA	DE
120.	11/17/2016	12948098	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001271	Expedited	75	Male	USA	DE
121.	11/18/2016	12955990	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001218	Expedited	80	Female	USA	DE
122.	11/18/2016	12953851	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001212	Expedited	72	Male	USA	DE
123.	11/18/2016	12953852	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001283	Expedited	89	Male	USA	DE
124.	11/18/2016	12953853	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001304	Expedited	89.12799	Female	USA	DE,OT
125.	11/18/2016	12955977	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001257	Expedited	68	Male	USA	DE
126.	11/18/2016	12955982	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001221	Expedited	NR	Male	USA	DE
127.	11/21/2016	12969944	1		Direct	80	Male	USA	DE
128.	11/23/2016	12967267	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001371	Expedited	77	Male	USA	DE,OT
129.	11/25/2016	12974459	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001311	Expedited	65.08	Female	USA	DE
130.	11/29/2016	12984322	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001378	Expedited	75.52	Male	USA	DE,HO
131.	11/29/2016	12984327	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001354	Expedited	82	Male	USA	DE
132.	11/30/2016	12986454	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001379	Expedited	79.58932	Female	USA	DE
133.	11/30/2016	12986455	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001382	Expedited	80	Male	USA	DE,OT
134.	12/1/2016	12989126	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001396	Expedited	80	Female	USA	DE
135.	12/1/2016	12989136	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001414	Expedited	81	Male	USA	DE,HO
136.	12/2/2016	12992586	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001365	Expedited	81.69	Male	USA	DE
137.	12/2/2016	12993947	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001417	Expedited	78.09993	Male	USA	DE
138.	12/2/2016	12993948	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001385	Expedited	65.48665	Male	USA	DE,HO
139.	12/2/2016	12993955	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001400	Expedited	69	Male	USA	DE
140.	12/7/2016	13005889	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001418	Expedited	77	Female	USA	DE,HO,OT
141.	12/9/2016	13011594	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001464	Expedited	NR	Null	USA	DE
142.	12/12/2016	13015667	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001496	Expedited	88	Male	USA	DE
143.	12/12/2016	13015671	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001474	Expedited	71	Male	USA	DE
144.	12/12/2016	13015672	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001476	Expedited	83	Female	USA	DE
145.	12/14/2016	13025416	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001533	Expedited	79	Male	USA	DE
146.	12/14/2016	13025418	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001521	Expedited	70	Male	USA	DE
147.	12/14/2016	13026546	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001516	Expedited	94.0835	Female	USA	DE
148.	12/15/2016	13029324	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001292	Expedited	82	Male	USA	DE
149.	12/19/2016	13039709	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001550	Expedited	79	Male	USA	DE
150.	12/19/2016	13039713	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001556	Expedited	74	Male	USA	DE
151.	12/19/2016	13039712	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001552	Expedited	65.09514	Female	USA	DE
152.	12/20/2016	13046023	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001583	Expedited	78	Female	USA	DE
153.	12/21/2016	13049781	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001597	Expedited	90	Male	USA	DE,HO
154.	12/21/2016	13049791	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001578	Expedited	79	Male	USA	DE,HO,OT
155.	12/22/2016	13053238	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001602	Expedited	80.04654	Male	USA	DE
156.	12/22/2016	13053240	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001569	Expedited	87	Female	USA	DE
157.	12/22/2016	13053246	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001591	Expedited	74.77892	Female	USA	DE

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	Initial FDA received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
158.	12/27/2016	13063445	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001633	Expedited	85	Male	USA	DE
159.	12/28/2016	13067625	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001667	Expedited	76	Male	USA	DE,HO
160.	12/28/2016	13067626	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001674	Expedited	71.35661	Male	USA	DE
161.	12/30/2016	13074431	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001694	Expedited	79	Male	USA	DE
162.	12/30/2016	13074443	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001704	Expedited	83.96441	Male	USA	DE,HO,OT
163.	1/4/2017	13083314	6	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001727	Expedited	83	Male	USA	DE,HO,OT
164.	1/4/2017	13083315	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001702	Expedited	76	Male	USA	DE
165.	1/4/2017	13083319	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001719	Expedited	74.88843	Male	USA	DE
166.	1/4/2017	13083320	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001711	Expedited	70	Female	USA	DE
167.	1/4/2017	13083321	5	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001706	Expedited	63	Female	USA	DE,HO,OT
168.	1/4/2017	13091985	1		Direct	81	Female	USA	DE
169.	1/5/2017	13087119	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001726	Expedited	70	Male	USA	DE
170.	1/6/2017	13094664	2	US-LUNDBECK-DKLU2024703	Expedited	81	Female	USA	DE
171.	1/9/2017	13097147	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001807	Expedited	72	Male	USA	DE,HO,OT
172.	1/9/2017	13097148	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001755	Expedited	76.23546	Male	USA	DE
173.	1/9/2017	13097151	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001730	Expedited	80	Female	USA	DE
174.	1/9/2017	13097153	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001758	Expedited	86.22587	Female	USA	DE
175.	1/9/2017	13097389	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001790	Expedited	66.19	Male	USA	DE,OT
176.	1/10/2017	13100095	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001770	Expedited	79.24435	Male	USA	DE
177.	1/10/2017	13101240	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001777	Expedited	75.8987	Male	USA	DE,HO,OT
178.	1/12/2017	13107597	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001804	Expedited	84.54757	Male	USA	DE
179.	1/12/2017	13107598	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001805	Expedited	81.25667	Female	USA	DE
180.	1/12/2017	13107601	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001817	Expedited	74	Male	USA	DE,HO
181.	1/16/2017	13118026	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001825	Expedited	77	Male	USA	DE
182.	1/16/2017	13118080	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001840	Expedited	58.83368	Male	USA	DE
183.	1/17/2017	13121828	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001827	Expedited	88	Male	USA	DE,OT
184.	1/17/2017	13121838	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001855	Expedited	88	Male	USA	DE,HO
185.	1/18/2017	13124050	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001841	Expedited	70.35181	Female	USA	DE,HO,OT
186.	1/20/2017	13133136	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001888	Expedited	72	Male	USA	DE,OT
187.	1/20/2017	13134386	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001876	Expedited	65.73306	Male	USA	DE
188.	1/20/2017	13134393	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001895	Expedited	73	Male	USA	DE
189.	1/23/2017	13136978	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001868	Expedited	85	Male	USA	DE
190.	1/23/2017	13136983	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001900	Expedited	81	Female	USA	DE
191.	1/23/2017	13136986	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001887	Expedited	72.97467	Male	USA	DE,HO
192.	1/23/2017	13136987	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001897	Expedited	87.95619	Male	USA	DE
193.	1/23/2017	13136988	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001890	Expedited	82	Female	USA	DE
194.	1/23/2017	13136994	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001905	Expedited	86	Male	USA	DE
195.	1/24/2017	13141983	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001964	Expedited	78.28063	Female	USA	DE
196.	1/24/2017	13141985	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001958	Expedited	84.70637	Female	USA	DE
197.	1/24/2017	13144812	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001939	Expedited	69.26762	Male	USA	DE,OT

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198.	1/25/2017	13149591	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001963	Expedited	83	Female	USA	DE
199.	1/25/2017	13149623	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001983	Expedited	79	Male	USA	DE
200.	1/26/2017	13153619	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001999	Expedited	85.97673	Male	USA	DE
201.	1/26/2017	13153722	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002002	Expedited	77.42094	Male	USA	DE
202.	1/27/2017	13158447	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001991	Expedited	82.91581	Male	USA	DE
203.	1/27/2017	13158448	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002003	Expedited	87.12389	Female	USA	DE,OT
204.	1/30/2017	13161730	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002027	Expedited	60	Male	USA	DE,HO,OT
205.	1/30/2017	13162662	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002048	Expedited	79	Female	USA	DE
206.	1/30/2017	13161729	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002041	Expedited	70.21492	Male	USA	DE
207.	1/30/2017	13162500	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002057	Expedited	87.82752	Female	USA	DE
208.	1/30/2017	13163156	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002036	Expedited	65	Male	USA	DE,HO
209.	1/31/2017	13167951	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002074	Expedited	88.11773	Female	USA	DE
210.	1/31/2017	13167953	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001493	Expedited	84	Male	USA	DE,HO
211.	2/1/2017	13175042	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002084	Expedited	79	Male	USA	DE,HO
212.	2/1/2017	13174347	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001645	Expedited	63	Female	USA	DE
213.	2/2/2017	13178263	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002068	Expedited	75.10746	Male	USA	DE
214.	2/2/2017	13178267	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002099	Expedited	96.10404	Female	USA	DE
215.	2/7/2017	13191360	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002127	Expedited	83	Male	USA	DE,HO
216.	2/7/2017	13191365	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002139	Expedited	79.36208	Male	USA	DE
217.	2/8/2017	13197198	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002136	Expedited	71	Male	USA	DE
218.	2/9/2017	13203066	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002142	Expedited	75	Male	USA	DE
219.	2/14/2017	13229282	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002173	Expedited	92	Male	USA	DE,OT
220.	2/14/2017	13229283	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002175	Expedited	73	Male	USA	DE
221.	2/14/2017	13229284	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002183	Expedited	74	Male	USA	DE,OT
222.	2/14/2017	13229287	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002207	Expedited	70	Male	USA	DE
223.	2/14/2017	13229290	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002195	Expedited	80	Female	USA	DE
224.	2/14/2017	13229291	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002218	Expedited	78	Male	USA	DE
225.	2/17/2017	13245511	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002227	Expedited	64	Male	USA	DE
226.	2/17/2017	13245556	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002233	Expedited	77	Male	USA	DE
227.	2/17/2017	13245820	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002213	Expedited	75	Male	USA	DE
228.	2/17/2017	13245827	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002211	Expedited	75	Male	USA	DE
229.	2/20/2017	13251010	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002240	Expedited	70	Male	USA	DE
230.	2/20/2017	13251011	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002248	Expedited	85	Male	USA	DE,HO
231.	2/20/2017	13251019	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002224	Expedited	84	Male	USA	DE
232.	2/20/2017	13252802	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001342	Expedited	77	Male	USA	DE
233.	2/20/2017	13252882	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001345	Expedited	76	Male	USA	DE,HO
234.	2/20/2017	13252923	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001162	Expedited	82	Male	USA	DE
235.	2/20/2017	13252929	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001327	Expedited	70	Male	USA	DE,HO
236.	2/20/2017	13253128	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001524	Expedited	65	Male	USA	DE
237.	2/20/2017	13253142	6	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001519	Expedited	92	Male	USA	DE,HO,OT

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238.	2/20/2017	13253165	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001555	Expedited	70	Male	USA	DE
239.	2/20/2017	13253184	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001601	Expedited	65	Male	USA	DE
240.	2/20/2017	13253243	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001683	Expedited	86	Female	USA	DE
241.	2/20/2017	13253253	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001581	Expedited	87	Female	USA	DE,HO
242.	2/20/2017	13253273	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001724	Expedited	78	Male	USA	DE,HO
243.	2/20/2017	13253365	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001280	Expedited	87	Male	USA	DE
244.	2/20/2017	13253405	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001788	Expedited	87	Male	USA	DE
245.	2/20/2017	13253446	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001795	Expedited	70	Female	USA	DE
246.	2/20/2017	13253461	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001834	Expedited	77	Female	USA	DE
247.	2/20/2017	13253467	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001877	Expedited	78	Female	USA	DE
248.	2/20/2017	13253480	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001850	Expedited	74	Male	USA	DE,OT
249.	2/20/2017	13253495	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001881	Expedited	78	Male	USA	DE
250.	2/20/2017	13253647	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002043	Expedited	88	Female	USA	DE,HO,OT
251.	2/20/2017	13253683	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002044	Expedited	76	Male	USA	DE
252.	2/20/2017	13253704	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002070	Expedited	75	Male	USA	DE
253.	2/20/2017	13253719	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001962	Expedited	64	Male	USA	DE
254.	2/20/2017	13251013	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001318	Expedited	75	Male	USA	DE
255.	2/20/2017	13252878	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001184	Expedited	77	Male	USA	DE
256.	2/20/2017	13252900	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001171	Expedited	NR	Female	USA	DE
257.	2/20/2017	13253013	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001457	Expedited	85.54	Male	USA	DE,HO,OT
258.	2/20/2017	13253152	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001535	Expedited	71.80287	Female	USA	DE
259.	2/20/2017	13253169	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001526	Expedited	79.28542	Male	USA	DE,HO
260.	2/20/2017	13253347	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001153	Expedited	80.87	Male	USA	DE,HO
261.	2/20/2017	13253411	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001778	Expedited	75.81	Male	USA	DE,HO
262.	2/20/2017	13253469	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001861	Expedited	86	Male	USA	DE
263.	2/21/2017	13254567	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002249	Expedited	74	Male	USA	DE
264.	2/21/2017	13254573	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002250	Expedited	83	Female	USA	DE
265.	2/21/2017	13254562	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001936	Expedited	69.72485	Female	USA	DE
266.	2/22/2017	13260265	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002256	Expedited	64	Male	USA	DE
267.	2/22/2017	13260671	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002272	Expedited	80	Male	USA	DE
268.	2/22/2017	13260678	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002296	Expedited	80	Male	USA	DE
269.	2/22/2017	13260263	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002278	Expedited	NR	Null	USA	DE
270.	2/23/2017	13263650	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002324	Expedited	NR	Female	USA	DE
271.	2/23/2017	13263651	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002289	Expedited	73	Male	USA	DE
272.	2/23/2017	13263655	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002304	Expedited	80	Male	USA	DE
273.	2/23/2017	13264235	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002315	Expedited	NR	Male	USA	DE
274.	2/27/2017	13273313	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002338	Expedited	83	Male	USA	DE,HO,OT
275.	2/28/2017	13276875	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002325	Expedited	82	Null	USA	DE
276.	2/28/2017	13276913	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002380	Expedited	81	Male	USA	DE
277.	2/28/2017	13276931	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002354	Expedited	83	Female	USA	DE

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278.	2/28/2017	13276935	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002379	Expedited	NR	Male	USA	DE
279.	2/28/2017	13276948	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002383	Expedited	79	Female	USA	DE
280.	3/1/2017	13280589	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002366	Expedited	79	Male	USA	DE
281.	3/3/2017	13292481	1		Direct	81	Male	USA	DE,HO
282.	3/6/2017	13296756	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002388	Expedited	71	Male	USA	DE,HO
283.	3/6/2017	13296759	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002200	Expedited	80	Male	USA	DE
284.	3/6/2017	13296765	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002403	Expedited	71	Male	USA	DE
285.	3/6/2017	13296768	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002420	Expedited	59	Male	USA	DE
286.	3/9/2017	13311917	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002478	Expedited	71	Male	USA	DE
287.	3/13/2017	13328362	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002599	Expedited	81	Male	USA	DE,HO
288.	3/13/2017	13328493	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002514	Expedited	85	Male	USA	DE
289.	3/14/2017	13330636	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002540	Expedited	82	Female	USA	DE
290.	3/14/2017	13330639	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002559	Expedited	65	Male	USA	DE
291.	3/15/2017	13335615	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002517	Expedited	74	Female	USA	DE
292.	3/15/2017	13337711	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002543	Expedited	85	Female	USA	DE
293.	3/16/2017	13342328	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002553	Expedited	89	Female	USA	DE,HO
294.	3/17/2017	13345711	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002572	Expedited	73	Male	USA	DE,OT
295.	3/17/2017	13345713	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002603	Expedited	79	Female	USA	DE
296.	3/17/2017	13345726	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002625	Expedited	78	Male	USA	DE,HO
297.	3/17/2017	13346308	1		Direct	58	Male	USA	DE
298.	3/20/2017	13350489	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002555	Expedited	83	Male	USA	DE,HO
299.	3/20/2017	13350490	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002593	Expedited	67	Male	USA	DE,HO
300.	3/20/2017	13350497	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002585	Expedited	81	Female	USA	DE
301.	3/20/2017	13350510	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002631	Expedited	71	Female	USA	DE
302.	3/21/2017	13355285	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002640	Expedited	64	Male	USA	DE,HO
303.	3/22/2017	13359167	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002634	Expedited	84	Male	USA	DE,HO
304.	3/23/2017	13363073	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002660	Expedited	89	Female	USA	DE
305.	3/24/2017	13367650	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002693	Expedited	86.76797	Female	USA	DE
306.	3/27/2017	13375274	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002217	Expedited	87	Male	USA	DE
307.	3/27/2017	13375275	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002699	Expedited	79	Female	USA	DE
308.	3/28/2017	13381498	1		Direct	71	Male	USA	DE
309.	3/30/2017	13386078	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002756	Expedited	79	Female	USA	DE
310.	3/30/2017	13386093	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002771	Expedited	69	Male	USA	DE,HO
311.	3/30/2017	13386095	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002754	Expedited	87	Male	USA	DE,HO
312.	3/30/2017	13386099	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002740	Expedited	82	Male	USA	DE,HO
313.	4/4/2017	13399223	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002804	Expedited	79	Male	USA	DE,HO,OT
314.	4/4/2017	13399228	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002769	Expedited	78	Male	USA	DE
315.	4/4/2017	13399250	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002768	Expedited	78	Male	USA	DE
316.	4/4/2017	13399251	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002797	Expedited	90	Male	USA	DE
317.	4/4/2017	13399257	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002802	Expedited	77	Female	USA	DE

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	Initial FDA received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
318.	4/4/2017	13399268	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002801	Expedited	76	Male	USA	DE,HO
319.	4/5/2017	13404245	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002819	Expedited	84	Male	USA	DE
320.	4/5/2017	13404250	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002817	Expedited	76	Male	USA	DE,HO
321.	4/7/2017	13414032	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002842	Expedited	76	Female	USA	DE
322.	4/7/2017	13414062	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002868	Expedited	73	Male	USA	DE
323.	4/11/2017	13425349	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002839	Expedited	89	Female	USA	DE
324.	4/11/2017	13425371	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002895	Expedited	73	Male	USA	DE
325.	4/11/2017	13425376	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002885	Expedited	74	Male	USA	DE
326.	4/12/2017	13432555	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002879	Expedited	78	Male	USA	DE,HO,OT
327.	4/12/2017	13432565	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002897	Expedited	75	Male	USA	DE
328.	4/12/2017	13434485	1		Direct	75.93	Male	USA	DE
329.	4/17/2017	13451900	1		Direct	75	Male	USA	DE
330.	4/18/2017	13452930	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002943	Expedited	62	Male	USA	DE
331.	4/18/2017	13452957	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002908	Expedited	84	Male	USA	DE,HO
332.	4/18/2017	13452958	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002904	Expedited	74	Male	USA	DE
333.	4/18/2017	13461753	1		Direct	76	Female	USA	DE
334.	4/19/2017	13458636	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002950	Expedited	71	Male	USA	DE,HO
335.	4/20/2017	13460829	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003006	Expedited	80	Female	USA	DE
336.	4/21/2017	13465568	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003034	Expedited	79	Male	USA	DE
337.	4/21/2017	13465569	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003033	Expedited	78	Male	USA	DE
338.	4/21/2017	13465570	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003027	Expedited	74	Female	USA	DE,OT
339.	4/21/2017	13465590	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003012	Expedited	77	Female	USA	DE,HO
340.	4/21/2017	13465606	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003039	Expedited	87	Male	USA	DE
341.	4/21/2017	13465608	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003037	Expedited	74	Male	USA	DE
342.	4/21/2017	13465633	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002971	Expedited	83	Male	USA	DE
343.	4/21/2017	13465666	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002483	Expedited	68	Male	USA	DE
344.	4/21/2017	13465668	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002967	Expedited	74	Male	USA	DE,HO
345.	4/21/2017	13465669	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002975	Expedited	79	Male	USA	DE,OT
346.	4/24/2017	13470727	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003080	Expedited	73	Male	USA	DE,HO
347.	4/24/2017	13470804	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003062	Expedited	80	Male	USA	DE
348.	4/24/2017	13470828	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003045	Expedited	87	Female	USA	DE,HO
349.	4/25/2017	13477742	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003164	Expedited	90	Female	USA	DE
350.	4/25/2017	13485093	1		Direct	61.99	Male	USA	DE
351.	4/26/2017	13482601	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003124	Expedited	73	Male	USA	DE
352.	4/27/2017	13495374	1		Direct	NR	Male	USA	DE
353.	5/1/2017	13498063	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003161	Expedited	81	Male	USA	DE
354.	5/1/2017	13498024	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001548	Expedited	72.47091	Male	USA	DE
355.	5/2/2017	13502049	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003180	Expedited	87	Male	USA	DE
356.	5/4/2017	13512879	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003195	Expedited	88	Female	USA	DE
357.	5/4/2017	13512885	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003176	Expedited	79	Male	USA	DE

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358.	5/4/2017	13515226	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003228	Expedited	78	Male	USA	DE
359.	5/4/2017	13515303	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003209	Expedited	74	Male	USA	DE,HO
360.	5/5/2017	13517117	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003248	Expedited	62	Male	USA	DE
361.	5/5/2017	13517124	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003246	Expedited	74	Male	USA	DE,HO,OT
362.	5/8/2017	13522310	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003270	Expedited	64	Female	USA	DE
363.	5/8/2017	13522311	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003265	Expedited	78	Female	USA	DE,HO
364.	5/8/2017	13522327	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003269	Expedited	74	Female	USA	DE
365.	5/9/2017	13526948	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003290	Expedited	77	Male	USA	DE
366.	5/9/2017	13526949	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003289	Expedited	84	Female	USA	DE
367.	5/9/2017	13526961	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003257	Expedited	94	Male	USA	DE
368.	5/9/2017	13526963	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003099	Expedited	76	Female	USA	DE,HO
369.	5/11/2017	13535806	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003343	Expedited	79	Male	USA	DE
370.	5/13/2017	13544762	1		Direct	88	Male	USA	DE
371.	5/15/2017	13544272	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002948	Expedited	83	Female	USA	DE,HO
372.	5/15/2017	13544293	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003318	Expedited	91	Male	USA	DE
373.	5/15/2017	13549687	1		Direct	77.3	Male	USA	DE
374.	5/16/2017	13549416	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003327	Expedited	71	Female	USA	DE
375.	5/16/2017	13549418	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003340	Expedited	NR	Male	USA	DE
376.	5/16/2017	13549503	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003329	Expedited	77	Male	USA	DE,OT
377.	5/16/2017	13549547	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003345	Expedited	88	Male	USA	DE
378.	5/16/2017	13549554	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003361	Expedited	81	Female	USA	DE
379.	5/16/2017	13549560	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003373	Expedited	79	Male	USA	DE
380.	5/16/2017	13552777	1		Direct	71	Male	USA	DE
381.	5/17/2017	13555816	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002330	Expedited	76	Female	USA	DE
382.	5/17/2017	13555909	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002451	Expedited	73	Male	USA	DE
383.	5/17/2017	13556222	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002503	Expedited	74	Male	USA	DE
384.	5/17/2017	13556332	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002462	Expedited	71	Male	USA	DE
385.	5/17/2017	13556444	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002480	Expedited	89	Female	USA	DE
386.	5/17/2017	13556826	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002469	Expedited	75	Female	USA	DE
387.	5/17/2017	13556933	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002624	Expedited	84	Male	USA	DE
388.	5/17/2017	13556967	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002674	Expedited	80	Male	USA	DE,HO,OT
389.	5/17/2017	13557248	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002856	Expedited	91	Male	USA	DE
390.	5/17/2017	13557409	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002915	Expedited	80	Male	USA	DE,HO
391.	5/17/2017	13557584	5	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003008	Expedited	73	Male	USA	DE
392.	5/17/2017	13557644	5	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003043	Expedited	80	Male	USA	DE,HO
393.	5/17/2017	13557772	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003112	Expedited	82	Male	USA	DE
394.	5/17/2017	13557774	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003127	Expedited	78	Female	USA	DE,HO
395.	5/17/2017	13557812	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003145	Expedited	74	Male	USA	DE
396.	5/17/2017	13557829	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003029	Expedited	81	Male	USA	DE
397.	5/17/2017	13557899	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003192	Expedited	82	Male	USA	DE

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398.	5/17/2017	13557911	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002494	Expedited	74	Male	USA	DE
399.	5/17/2017	13557981	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003224	Expedited	72	Female	USA	DE,HO,OT
400.	5/18/2017	13559835	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003369	Expedited	77	Female	USA	DE
401.	5/18/2017	13559845	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003394	Expedited	84	Female	USA	DE
402.	5/18/2017	13559848	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003381	Expedited	78	Female	USA	DE
403.	5/18/2017	13559858	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003363	Expedited	76	Female	USA	DE
404.	5/18/2017	13559885	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003439	Expedited	73	Female	USA	DE
405.	5/19/2017	13563703	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003488	Expedited	82	Male	USA	DE
406.	5/19/2017	13563762	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003485	Expedited	85	Male	USA	DE
407.	5/22/2017	13566701	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003475	Expedited	67	Male	USA	DE
408.	5/22/2017	13566707	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003492	Expedited	86	Male	USA	DE
409.	5/22/2017	13566709	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003493	Expedited	74	Male	USA	DE
410.	5/23/2017	13571012	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003489	Expedited	84	Female	USA	DE
411.	5/23/2017	13571015	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003487	Expedited	65	Male	USA	DE
412.	5/23/2017	13571018	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003501	Expedited	69	Male	USA	DE,HO
413.	5/24/2017	13575523	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003514	Expedited	66	Male	USA	DE
414.	5/24/2017	13575535	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003511	Expedited	66	Male	USA	DE
415.	5/24/2017	13575541	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003522	Expedited	90	Male	USA	DE
416.	5/24/2017	13575546	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003527	Expedited	89	Female	USA	DE
417.	5/25/2017	13586637	1		Direct	86	Male	USA	DE
418.	5/29/2017	13590562	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003555	Expedited	84	Male	USA	DE
419.	5/29/2017	13590564	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003554	Expedited	71	Male	USA	DE
420.	5/29/2017	13590567	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003536	Expedited	77	Male	USA	DE
421.	5/29/2017	13590571	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003553	Expedited	73	Male	USA	DE
422.	5/30/2017	13590232	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003546	Expedited	93	Male	USA	DE
423.	5/30/2017	13590273	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003568	Expedited	71	Male	USA	DE
424.	5/31/2017	13595234	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003572	Expedited	81	Female	USA	DE,OT
425.	6/2/2017	13607375	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003607	Expedited	81	Male	USA	DE
426.	6/6/2017	13614491	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003656	Expedited	88	Male	USA	DE,OT
427.	6/7/2017	13625911	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003657	Expedited	69	Male	USA	DE,HO,OT
428.	6/9/2017	13641411	1		Direct	NR	Male	USA	DE
429.	6/13/2017	13645885	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003716	Expedited	80	Female	USA	DE
430.	6/14/2017	13649948	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003743	Expedited	67	Male	USA	DE
431.	6/14/2017	13649961	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003754	Expedited	78	Female	USA	DE
432.	6/14/2017	13649981	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003764	Expedited	86	Female	USA	DE
433.	6/15/2017	13655138	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003780	Expedited	87	Female	USA	DE
434.	6/15/2017	13655148	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003751	Expedited	67	Female	USA	DE
435.	6/16/2017	13659483	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003774	Expedited	86	Female	USA	DE
436.	6/19/2017	13663265	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003865	Expedited	80	Male	USA	DE
437.	6/19/2017	13663266	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003804	Expedited	82	Male	USA	DE

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438.	6/19/2017	13663267	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003831	Expedited	85	Female	USA	DE
439.	6/20/2017	13668469	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003829	Expedited	76	Female	USA	DE,HO,LT, OT
440.	6/20/2017	13668471	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003863	Expedited	77	Female	USA	DE,HO
441.	6/20/2017	13668479	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003858	Expedited	70	Male	USA	DE
442.	6/20/2017	13668483	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003854	Expedited	80	Female	USA	DE,HO,OT
443.	6/22/2017	13676223	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003895	Expedited	77	Male	USA	DE
444.	6/22/2017	13676224	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003897	Expedited	94	Female	USA	DE
445.	6/22/2017	13676222	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003928	Expedited	NR	Null	USA	DE
446.	6/22/2017	13681827	1		Direct	89	Male	USA	DE
447.	6/23/2017	13680782	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004113	Expedited	60	Male	USA	DE
448.	6/26/2017	13688049	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004146	Expedited	70	Female	USA	DE
449.	6/26/2017	13688053	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004126	Expedited	79	Male	USA	DE,OT
450.	6/27/2017	13693299	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004246	Expedited	83	Male	USA	DE
451.	6/27/2017	13693304	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004049	Expedited	77	Female	USA	DE
452.	6/28/2017	13697813	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004169	Expedited	84	Male	USA	DE
453.	6/28/2017	13697833	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004240	Expedited	82	Female	USA	DE
454.	6/28/2017	13697840	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004241	Expedited	64	Male	USA	DE,HO
455.	6/30/2017	13704427	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004326	Expedited	86	Male	USA	DE
456.	6/30/2017	13704428	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003919	Expedited	81	Female	USA	DE
457.	6/30/2017	13704437	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004376	Expedited	77	Male	USA	DE
458.	7/3/2017	13709650	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004387	Expedited	81	Female	USA	DE
459.	7/3/2017	13709664	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004286	Expedited	77	Male	USA	DE
460.	7/4/2017	13713445	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004419	Expedited	79	Male	USA	DE,HO
461.	7/4/2017	13713453	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004434	Expedited	89	Male	USA	DE
462.	7/5/2017	13716297	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004557	Expedited	70	Male	USA	DE
463.	7/5/2017	13716324	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004461	Expedited	85	Male	USA	DE
464.	7/5/2017	13716333	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004458	Expedited	83	Male	USA	DE
465.	7/7/2017	13727224	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004487	Expedited	67	Male	USA	DE
466.	7/10/2017	13736295	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004503	Expedited	96	Male	USA	DE
467.	7/10/2017	13736297	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004515	Expedited	74	Male	USA	DE
468.	7/10/2017	13736301	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004517	Expedited	71	Female	USA	DE
469.	7/12/2017	13744262	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004521	Expedited	78	Male	USA	DE,HO
470.	7/12/2017	13745410	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004544	Expedited	87	Male	USA	DE
471.	7/12/2017	13745426	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004542	Expedited	93	Female	USA	DE,HO
472.	7/14/2017	13752890	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004577	Expedited	85	Male	USA	DE
473.	7/14/2017	13753028	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004576	Expedited	78	Female	USA	DE
474.	7/17/2017	13757874	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004593	Expedited	80	Male	USA	DE
475.	7/18/2017	13763290	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004613	Expedited	91	Male	USA	DE
476.	7/18/2017	13763306	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004595	Expedited	66	Male	USA	DE

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	Initial FDA received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
477.	7/20/2017	13771321	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004625	Expedited	74	Male	USA	DE
478.	7/20/2017	13771328	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004599	Expedited	72	Male	USA	DE,OT
479.	7/20/2017	13771329	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004631	Expedited	74	Male	USA	DE,HO,OT
480.	7/20/2017	13771330	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004646	Expedited	73	Female	USA	DE,HO
481.	7/24/2017	13781016	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004683	Expedited	81	Female	USA	DE
482.	7/24/2017	13781027	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004694	Expedited	63	Male	USA	DE
483.	7/26/2017	13795823	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004720	Expedited	77	Male	USA	DE,OT
484.	7/26/2017	13795832	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004744	Expedited	75	Male	USA	DE
485.	7/26/2017	13795833	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004756	Expedited	90	Male	USA	DE
486.	7/26/2017	13795840	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004730	Expedited	74	Male	USA	DE
487.	7/31/2017	13814965	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004763	Expedited	92	Female	USA	DE
488.	7/31/2017	13815440	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003590	Expedited	72	Male	USA	DE,HO,OT
489.	8/1/2017	13825252	1		Direct	68.68	Male	USA	DE
490.	8/2/2017	13824859	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004799	Expedited	72	Female	USA	DE
491.	8/2/2017	13824867	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004817	Expedited	86	Female	USA	DE
492.	8/2/2017	13824914	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004814	Expedited	85	Male	USA	DE
493.	8/2/2017	13824983	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004833	Expedited	88	Female	USA	DE
494.	8/2/2017	13824984	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004832	Expedited	79	Male	USA	DE
495.	8/4/2017	13834134	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004847	Expedited	84	Male	USA	DE
496.	8/4/2017	13834136	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004846	Expedited	71	Male	USA	DE,HO
497.	8/4/2017	13834143	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004842	Expedited	79	Male	USA	DE
498.	8/4/2017	13834151	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004862	Expedited	77	Female	USA	DE
499.	8/4/2017	13834156	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004502	Expedited	71	Male	USA	DE
500.	8/8/2017	13843950	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005010	Expedited	73	Male	USA	DE
501.	8/9/2017	13848757	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004902	Expedited	73	Female	USA	DE
502.	8/9/2017	13848758	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004925	Expedited	66	Female	USA	DE
503.	8/9/2017	13848763	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004888	Expedited	94	Male	USA	DE,HO
504.	8/10/2017	13851821	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000413	Expedited	73	Female	USA	DE
505.	8/11/2017	13857647	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004979	Expedited	82	Female	USA	DE,HO
506.	8/14/2017	13863042	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004997	Expedited	74	Female	USA	DE
507.	8/14/2017	13863067	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004956	Expedited	94	Female	USA	DE,HO,OT
508.	8/14/2017	13863068	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004991	Expedited	69	Male	USA	DE
509.	8/14/2017	13865398	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003798	Expedited	76	Male	USA	DE,OT
510.	8/14/2017	13866753	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004307	Expedited	85	Female	USA	DE
511.	8/14/2017	13866792	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004457	Expedited	73	Male	USA	DE,HO,OT
512.	8/14/2017	13866812	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004473	Expedited	75	Female	USA	DE
513.	8/14/2017	13866919	6	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003731	Expedited	86	Male	USA	DE,HO
514.	8/14/2017	13867078	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003903	Expedited	81	Male	USA	DE
515.	8/14/2017	13867240	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004644	Expedited	76	Male	USA	DE
516.	8/14/2017	13867346	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004721	Expedited	71	Female	USA	DE

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517.	8/14/2017	13867366	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004729	Expedited	72	Male	USA	DE
518.	8/14/2017	13867510	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004792	Expedited	86	Male	USA	DE,HO
519.	8/14/2017	13867568	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004815	Expedited	81	Female	USA	DE
520.	8/14/2017	13867664	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004879	Expedited	73	Male	USA	DE
521.	8/14/2017	13867672	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003349	Expedited	82	Female	USA	DE
522.	8/14/2017	13867689	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003383	Expedited	81	Female	USA	DE,HO
523.	8/14/2017	13867801	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003611	Expedited	87	Male	USA	DE
524.	8/14/2017	13867840	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003701	Expedited	80	Male	USA	DE
525.	8/14/2017	13867856	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003728	Expedited	89	Male	USA	DE
526.	8/14/2017	13867865	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003631	Expedited	74	Male	USA	DE
527.	8/14/2017	13867934	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004313	Expedited	79	Female	USA	DE
528.	8/14/2017	13867999	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003303	Expedited	71	Male	USA	DE,OT
529.	8/14/2017	13868034	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004629	Expedited	81	Male	USA	DE
530.	8/14/2017	13868106	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004913	Expedited	73	Male	USA	DE
531.	8/14/2017	13868146	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004920	Expedited	79	Male	USA	DE
532.	8/15/2017	13868525	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005013	Expedited	81	Male	USA	DE
533.	8/15/2017	13868530	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005006	Expedited	90	Male	USA	DE
534.	8/15/2017	13868541	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005011	Expedited	75	Male	USA	DE,HO
535.	8/16/2017	13871439	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005039	Expedited	85	Male	USA	DE
536.	8/16/2017	13871479	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005032	Expedited	67	Male	USA	DE
537.	8/17/2017	13876842	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005043	Expedited	81	Male	USA	DE
538.	8/17/2017	13876867	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005048	Expedited	79	Male	USA	DE,HO
539.	8/18/2017	13880412	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005087	Expedited	47	Male	USA	DE,HO
540.	8/18/2017	13880438	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005081	Expedited	86	Male	USA	DE,HO
541.	8/22/2017	13890749	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005101	Expedited	81	Female	USA	DE
542.	8/22/2017	13890780	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005092	Expedited	63	Female	USA	DE
543.	8/22/2017	13890798	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005121	Expedited	78	Female	USA	DE
544.	8/23/2017	13896142	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005115	Expedited	52	Female	USA	DE
545.	8/23/2017	13896239	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005105	Expedited	83	Male	USA	DE
546.	8/23/2017	13896247	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005140	Expedited	82	Male	USA	DE
547.	8/24/2017	13900164	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005136	Expedited	79	Male	USA	DE
548.	8/28/2017	13909302	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005183	Expedited	84	Female	USA	DE
549.	8/28/2017	13909311	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005182	Expedited	87	Male	USA	DE,HO,OT
550.	8/28/2017	13909315	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005171	Expedited	80	Male	USA	DE
551.	8/28/2017	13909316	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005188	Expedited	71	Male	USA	DE
552.	8/28/2017	13909319	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005161	Expedited	79	Male	USA	DE,OT
553.	8/29/2017	13914450	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005229	Expedited	71	Male	USA	DE,HO
554.	8/30/2017	13919334	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005231	Expedited	83	Male	USA	DE
555.	8/30/2017	13919335	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005216	Expedited	80	Male	USA	DE
556.	8/30/2017	13919346	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005232	Expedited	95	Male	USA	DE

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557.	8/30/2017	13919359	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005257	Expedited	74	Male	USA	DE
558.	9/5/2017	13936125	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005127	Expedited	75	Female	USA	DE
559.	9/5/2017	13936138	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005301	Expedited	82	Male	USA	DE
560.	9/6/2017	13940990	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005341	Expedited	83	Male	USA	DE
561.	9/7/2017	13941957	1		Direct	80.08	Male	USA	DE
562.	9/11/2017	13955369	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005368	Expedited	86	Male	USA	DE
563.	9/11/2017	13955453	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005382	Expedited	96	Female	USA	DE
564.	9/13/2017	13964379	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005406	Expedited	74	Male	USA	DE,OT
565.	9/13/2017	13964385	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005422	Expedited	78	Male	USA	DE
566.	9/13/2017	13964421	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005405	Expedited	68	Male	USA	DE
567.	9/18/2017	13982195	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005305	Expedited	97	Female	USA	DE,HO
568.	9/20/2017	13992928	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005484	Expedited	63	Female	USA	DE,OT
569.	9/20/2017	13993074	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005466	Expedited	80	Male	USA	DE
570.	9/20/2017	13993111	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005283	Expedited	83	Female	USA	DE
571.	9/20/2017	13993250	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005450	Expedited	77	Female	USA	DE
572.	9/20/2017	13993561	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005469	Expedited	77	Female	USA	DE
573.	9/22/2017	13998937	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005474	Expedited	83	Male	USA	DE,HO
574.	9/22/2017	13998962	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005480	Expedited	81	Female	USA	DE
575.	9/22/2017	13999605	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005495	Expedited	74	Male	USA	DE,HO
576.	9/22/2017	14000448	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005503	Expedited	72	Female	USA	DE
577.	9/22/2017	14000467	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005502	Expedited	78	Female	USA	DE
578.	9/26/2017	14011905	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005527	Expedited	78	Male	USA	DE,HO
579.	9/26/2017	14011926	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005526	Expedited	84	Male	USA	DE,HO
580.	9/26/2017	14012199	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005530	Expedited	78	Male	USA	DE
581.	9/26/2017	14012550	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005523	Expedited	78	Female	USA	DE,HO,OT
582.	9/26/2017	14012805	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005544	Expedited	90	Female	USA	DE
583.	9/27/2017	14016890	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005555	Expedited	76	Male	USA	DE,OT
584.	9/27/2017	14016906	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005545	Expedited	80	Male	USA	DE
585.	9/27/2017	14017051	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005532	Expedited	75	Male	USA	DE
586.	9/27/2017	14017084	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005640	Expedited	81	Female	USA	DE
587.	9/28/2017	14019830	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005570	Expedited	79	Female	USA	DE
588.	9/28/2017	14019831	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005559	Expedited	87	Male	USA	DE,HO,OT
589.	9/28/2017	14019832	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005590	Expedited	75	Female	USA	DE
590.	9/29/2017	14022900	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005591	Expedited	88	Male	USA	DE
591.	10/2/2017	14031935	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005594	Expedited	74	Female	USA	DE,HO,OT
592.	10/2/2017	14031937	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005722	Expedited	90	Female	USA	DE
593.	10/2/2017	14031957	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005596	Expedited	73	Male	USA	DE
594.	10/3/2017	14032474	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005623	Expedited	84	Male	USA	DE
595.	10/3/2017	14032516	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005636	Expedited	71	Female	USA	DE
596.	10/3/2017	14032459	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005167	Expedited	95.15674	Female	USA	DE

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597.	10/4/2017	14038117	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005307	Expedited	79	Female	USA	DE
598.	10/4/2017	14038121	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005630	Expedited	81	Male	USA	DE,HO,OT
599.	10/4/2017	14038142	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005648	Expedited	73	Male	USA	DE
600.	10/4/2017	14038158	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005019	Expedited	77	Male	USA	DE
601.	10/5/2017	14046628	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005654	Expedited	84	Male	USA	DE
602.	10/5/2017	14046756	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005677	Expedited	69	Male	USA	DE
603.	10/6/2017	14053787	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005685	Expedited	88	Male	USA	DE
604.	10/6/2017	14053873	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005695	Expedited	80	Male	USA	DE,HO
605.	10/10/2017	14068318	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005659	Expedited	79	Male	USA	DE
606.	10/10/2017	14068352	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003624	Expedited	78	Male	USA	DE,OT
607.	10/10/2017	14068354	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005790	Expedited	62	Male	USA	DE
608.	10/13/2017	14081461	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005680	Expedited	67	Female	USA	DE
609.	10/13/2017	14081524	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005765	Expedited	72	Female	USA	DE
610.	10/16/2017	14092899	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005805	Expedited	90	Male	USA	DE
611.	10/16/2017	14096887	1		Direct	83	Male	USA	DE
612.	10/18/2017	14102132	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005822	Expedited	80	Male	USA	DE
613.	10/18/2017	14102159	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005841	Expedited	75	Male	USA	DE
614.	10/20/2017	14110255	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005985	Expedited	77	Male	USA	DE
615.	10/23/2017	14114275	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005874	Expedited	70	Female	USA	DE
616.	10/23/2017	14114279	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005881	Expedited	57	Male	USA	DE
617.	10/23/2017	14114282	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005888	Expedited	71	Male	USA	DE
618.	10/23/2017	14114290	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005901	Expedited	72	Male	USA	DE
619.	10/23/2017	14119055	1		Direct	NR	Female	USA	DE
620.	10/25/2017	14124101	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005929	Expedited	80	Female	USA	DE
621.	10/27/2017	14134916	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005099	Expedited	81	Male	USA	DE,HO
622.	10/27/2017	14135023	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005951	Expedited	88	Female	USA	DE
623.	10/27/2017	14135061	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005969	Expedited	84	Female	USA	DE
624.	10/27/2017	14135074	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005953	Expedited	83	Male	USA	DE
625.	10/27/2017	14135151	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005960	Expedited	76	Male	USA	DE
626.	10/27/2017	14135183	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005963	Expedited	88	Male	USA	DE,HO
627.	10/30/2017	14142168	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005977	Expedited	82	Male	USA	DE
628.	10/30/2017	14142212	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005981	Expedited	84	Female	USA	DE
629.	10/30/2017	14142214	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005982	Expedited	86	Male	USA	DE
630.	10/30/2017	14144401	1		Direct	82	Male	USA	DE
631.	11/1/2017	14149236	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005989	Expedited	88	Male	USA	DE
632.	11/1/2017	14149279	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005993	Expedited	74	Male	USA	DE,HO
633.	11/1/2017	14149316	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006004	Expedited	72	Male	USA	DE
634.	11/1/2017	14151918	1		Direct	96	Female	USA	DE
635.	11/3/2017	14156015	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006029	Expedited	72	Male	USA	DE,HO
636.	11/3/2017	14156056	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006033	Expedited	95	Female	USA	DE

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	Initial FDA received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
637.	11/3/2017	14156061	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006041	Expedited	80	Male	USA	DE
638.	11/6/2017	14161319	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006046	Expedited	79	Female	USA	DE
639.	11/6/2017	14161387	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006048	Expedited	83	Male	USA	DE,HO
640.	11/6/2017	14161420	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006060	Expedited	76	Male	USA	DE
641.	11/6/2017	14161819	2	US-PFIZER INC-2017475647	Expedited	76	Male	USA	DE
642.	11/9/2017	14172161	5	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005897	Expedited	77	Male	USA	DE,HO
643.	11/9/2017	14172621	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005076	Expedited	64	Female	USA	DE
644.	11/9/2017	14174392	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005419	Expedited	79	Male	USA	DE
645.	11/9/2017	14174492	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006088	Expedited	70	Male	USA	DE
646.	11/9/2017	14174545	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006117	Expedited	88	Male	USA	DE
647.	11/9/2017	14174552	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006093	Expedited	84	Female	USA	DE
648.	11/9/2017	14174564	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005883	Expedited	67	Male	USA	DE
649.	11/10/2017	14177552	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004959	Expedited	65	Female	USA	DE
650.	11/10/2017	14177877	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005812	Expedited	79	Female	USA	DE
651.	11/10/2017	14178084	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005348	Expedited	71	Male	USA	DE
652.	11/10/2017	14178269	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005409	Expedited	73	Male	USA	DE
653.	11/10/2017	14178369	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005522	Expedited	81	Female	USA	DE,HO
654.	11/10/2017	14178776	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005886	Expedited	82	Female	USA	DE,OT
655.	11/10/2017	14179303	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006011	Expedited	92.12	Female	USA	DE
656.	11/11/2017	14178462	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005988	Expedited	78	Male	USA	DE
657.	11/11/2017	14178647	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005639	Expedited	89	Female	USA	DE
658.	11/14/2017	14185099	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006139	Expedited	86.69131	Female	USA	DE
659.	11/14/2017	14185104	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006149	Expedited	77	Male	USA	DE
660.	11/14/2017	14185116	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006146	Expedited	76	Female	USA	DE
661.	11/14/2017	14185120	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006150	Expedited	70	Male	USA	DE
662.	11/20/2017	14208530	1		Direct	80	Male	USA	DE
663.	11/21/2017	14206953	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006114	Expedited	92	Male	USA	DE
664.	11/21/2017	14206954	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006229	Expedited	59	Male	USA	DE
665.	11/21/2017	14206955	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003699	Expedited	69	Male	USA	DE,HO
666.	11/21/2017	14206956	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006207	Expedited	76	Female	USA	DE
667.	11/21/2017	14206964	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006268	Expedited	77	Female	USA	DE
668.	11/22/2017	14212154	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006266	Expedited	73	Male	USA	DE,HO
669.	11/24/2017	14220611	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006287	Expedited	NR	Male	USA	DE
670.	11/27/2017	14225249	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006339	Expedited	83	Male	USA	DE
671.	11/27/2017	14225250	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006306	Expedited	76	Male	USA	DE
672.	11/27/2017	14225255	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006326	Expedited	82	Male	USA	DE
673.	11/27/2017	14225257	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006296	Expedited	78	Male	USA	DE
674.	11/27/2017	14225261	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006294	Expedited	79	Male	USA	DE
675.	11/29/2017	14235104	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006338	Expedited	79	Male	USA	DE
676.	11/29/2017	14235114	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006305	Expedited	91	Female	USA	DE,HO

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677.	11/29/2017	14235116	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006364	Expedited	82	Female	USA	DE
678.	11/29/2017	14235121	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006350	Expedited	71	Male	USA	DE
679.	11/29/2017	14235136	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006349	Expedited	84	Male	USA	DE,HO
680.	11/29/2017	14238948	1		Direct	68	Female	USA	DE
681.	11/30/2017	14239436	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006405	Expedited	79	Male	USA	DE
682.	11/30/2017	14240465	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006411	Expedited	71	Male	USA	DE
683.	11/30/2017	14240481	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006429	Expedited	76	Male	USA	DE
684.	12/1/2017	14242758	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006417	Expedited	83	Male	USA	DE,HO,OT
685.	12/5/2017	14253142	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006423	Expedited	75	Female	USA	DE
686.	12/5/2017	14253167	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006443	Expedited	80	Male	USA	DE
687.	12/5/2017	14253169	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006446	Expedited	77	Female	USA	DE,HO
688.	12/5/2017	14253174	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006441	Expedited	83	Male	USA	DE,HO
689.	12/5/2017	14253192	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006451	Expedited	79	Male	USA	DE
690.	12/6/2017	14256289	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006463	Expedited	87	Male	USA	DE
691.	12/8/2017	14263315	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006516	Expedited	81	Male	USA	DE
692.	12/8/2017	14263316	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006500	Expedited	78	Female	USA	DE,HO
693.	12/12/2017	14277224	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006536	Expedited	75	Male	USA	DE
694.	12/12/2017	14280278	1		Direct	71	Male	USA	DE
695.	12/13/2017	14283152	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006560	Expedited	85	Male	USA	DE
696.	12/13/2017	14283153	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006617	Expedited	88	Male	USA	DE
697.	12/13/2017	14283154	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006554	Expedited	85	Male	USA	DE
698.	12/13/2017	14283157	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006599	Expedited	84	Female	USA	DE
699.	12/13/2017	14283160	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006538	Expedited	78	Female	USA	DE
700.	12/13/2017	14283162	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006609	Expedited	76	Male	USA	DE
701.	12/14/2017	14289055	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006691	Expedited	NR	Male	USA	DE
702.	12/14/2017	14289057	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006631	Expedited	72	Male	USA	DE
703.	12/14/2017	14289062	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006607	Expedited	NR	Male	USA	DE
704.	12/14/2017	14289064	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006571	Expedited	83	Male	USA	DE,HO
705.	12/14/2017	14289066	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006570	Expedited	94	Male	USA	DE
706.	12/14/2017	14289083	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006653	Expedited	80	Male	USA	DE
707.	12/15/2017	14291165	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006635	Expedited	71	Female	USA	DE
708.	12/15/2017	14291178	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006646	Expedited	73	Male	USA	DE
709.	12/19/2017	14303067	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006722	Expedited	83	Male	USA	DE
710.	12/19/2017	14303068	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006688	Expedited	81	Female	USA	DE
711.	12/19/2017	14303069	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006698	Expedited	77	Male	USA	DE
712.	12/19/2017	14303074	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006711	Expedited	NR	Male	USA	DE
713.	12/19/2017	14303075	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006677	Expedited	79	Male	USA	DE
714.	12/19/2017	14303080	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006678	Expedited	78	Male	USA	DE,OT
715.	12/19/2017	14303081	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006748	Expedited	NR	Male	USA	DE
716.	12/19/2017	14303087	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006705	Expedited	75	Male	USA	DE

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717.	12/19/2017	14303088	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006750	Expedited	80	Male	USA	DE
718.	12/19/2017	14303090	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006755	Expedited	86	Female	USA	DE
719.	12/19/2017	14303091	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006741	Expedited	NR	Female	USA	DE
720.	12/19/2017	14303095	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006309	Expedited	80	Female	USA	DE
721.	12/19/2017	14303096	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006718	Expedited	75	Male	USA	DE
722.	12/20/2017	14309615	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006702	Expedited	71	Male	USA	DE
723.	12/20/2017	14312915	1		Direct	87	Male	USA	DE
724.	12/21/2017	14313322	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006776	Expedited	79	Male	USA	DE
725.	12/21/2017	14313330	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006770	Expedited	87	Male	USA	DE
726.	12/21/2017	14313336	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006778	Expedited	78	Male	USA	DE
727.	12/22/2017	14318701	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006787	Expedited	86	Female	USA	DE,HO
728.	12/26/2017	14324981	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006802	Expedited	64	Female	USA	DE
729.	12/26/2017	14324982	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006373	Expedited	86	Male	USA	DE,OT
730.	12/26/2017	14325231	3	US-NEUROCRINE BIOSCIENCES INC.-2017NBI02023	Non-Expedited	87	Male	USA	DE,HO
731.	12/27/2017	14330279	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006810	Expedited	NR	Female	USA	DE
732.	12/27/2017	14330280	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006826	Expedited	70	Male	USA	DE
733.	12/28/2017	14332736	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006840	Expedited	65	Male	USA	DE
734.	12/28/2017	14332741	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006474	Expedited	75	Male	USA	DE,HO
735.	12/28/2017	14332742	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006844	Expedited	83	Female	USA	DE
736.	12/28/2017	14338056	1		Direct	91	Male	USA	DE
737.	1/2/2018	14342236	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006888	Expedited	72	Male	USA	DE
738.	1/2/2018	14342363	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006884	Expedited	71	Male	USA	DE
739.	1/3/2018	14346163	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006919	Expedited	91	Male	USA	DE
740.	1/4/2018	14349907	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006934	Expedited	81	Male	USA	DE
741.	1/4/2018	14349910	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006926	Expedited	88	Female	USA	DE
742.	1/5/2018	14354952	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-006957	Expedited	82	Male	USA	DE
743.	1/5/2018	14354954	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-006956	Expedited	86	Male	USA	DE
744.	1/8/2018	14363667	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-006978	Expedited	76	Male	USA	DE
745.	1/8/2018	14363669	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-006969	Expedited	66	Male	USA	DE
746.	1/8/2018	14363671	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-006976	Expedited	70	Male	USA	DE
747.	1/8/2018	14363674	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006092	Expedited	82	Female	USA	DE,HO
748.	1/8/2018	14363676	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-006960	Expedited	84	Female	USA	DE
749.	1/9/2018	14367500	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007002	Expedited	80	Male	USA	DE
750.	1/10/2018	14372847	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-006993	Expedited	76	Male	USA	DE
751.	1/10/2018	14372850	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007007	Expedited	77	Male	USA	DE
752.	1/10/2018	14376951	1		Direct	76	Male	USA	DE
753.	1/11/2018	14376832	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007033	Expedited	86	Female	USA	DE
754.	1/11/2018	14376833	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-006990	Expedited	72	Male	USA	DE
755.	1/11/2018	14376834	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007036	Expedited	79	Male	USA	DE

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756.	1/11/2018	14376835	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007034	Expedited	85	Female	USA	DE
757.	1/12/2018	14382032	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007050	Expedited	87	Male	USA	DE
758.	1/12/2018	14382038	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007045	Expedited	68	Male	USA	DE
759.	1/12/2018	14382039	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007043	Expedited	78	Male	USA	DE
760.	1/12/2018	14382040	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007055	Expedited	72	Male	USA	DE
761.	1/12/2018	14382045	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007054	Expedited	76	Male	USA	DE
762.	1/12/2018	14391733	1		Direct	77	Male	USA	DE
763.	1/13/2018	14401063	1		Direct	89	Female	USA	DE
764.	1/15/2018	14385085	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007067	Expedited	79	Female	USA	DE
765.	1/15/2018	14385086	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007071	Expedited	83	Female	USA	DE
766.	1/15/2018	14385090	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007046	Expedited	85	Female	USA	DE,HO
767.	1/15/2018	14385118	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007048	Expedited	85	Male	USA	DE
768.	1/15/2018	14385134	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007063	Expedited	84	Female	USA	DE
769.	1/15/2018	14385135	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007068	Expedited	84	Male	USA	DE
770.	1/16/2018	14393613	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007094	Expedited	71	Female	USA	DE
771.	1/16/2018	14393614	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007110	Expedited	81	Male	USA	DE
772.	1/16/2018	14393615	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007107	Expedited	91	Male	USA	DE
773.	1/16/2018	14393616	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007085	Expedited	74	Male	USA	DE,HO
774.	1/16/2018	14393617	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007092	Expedited	83	Male	USA	DE
775.	1/16/2018	14393618	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007053	Expedited	80	Male	USA	DE
776.	1/16/2018	14393622	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007078	Expedited	73	Male	USA	DE
777.	1/16/2018	14406955	1		Direct	81	Male	USA	DE
778.	1/17/2018	14403842	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007111	Expedited	70	Male	USA	DE
779.	1/17/2018	14403843	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007122	Expedited	81	Male	USA	DE,HO
780.	1/17/2018	14403850	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007100	Expedited	68	Male	USA	DE
781.	1/18/2018	14408255	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007145	Expedited	76	Female	USA	DE
782.	1/18/2018	14408262	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007147	Expedited	80	Male	USA	DE
783.	1/18/2018	14408263	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007151	Expedited	80	Male	USA	DE
784.	1/18/2018	14408265	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007124	Expedited	64	Female	USA	DE
785.	1/19/2018	14410807	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006845	Expedited	62	Male	USA	DE
786.	1/19/2018	14410808	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006816	Expedited	89	Female	USA	DE
787.	1/19/2018	14410809	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007161	Expedited	82	Female	USA	DE
788.	1/19/2018	14410810	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007180	Expedited	66	Male	USA	DE
789.	1/19/2018	14410811	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007171	Expedited	73	Male	USA	DE
790.	1/19/2018	14410812	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007179	Expedited	76	Female	USA	DE
791.	1/19/2018	14410813	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007173	Expedited	90	Male	USA	DE
792.	1/19/2018	14410817	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007134	Expedited	74	Male	USA	DE
793.	1/22/2018	14418179	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007189	Expedited	77	Male	USA	DE
794.	1/22/2018	14418189	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007188	Expedited	84	Male	USA	DE
795.	1/22/2018	14418190	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007172	Expedited	78	Male	USA	DE

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	Initial FDA received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
796.	1/23/2018	14424952	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007132	Expedited	74	Male	USA	DE
797.	1/23/2018	14424958	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007197	Expedited	88	Male	USA	DE,HO
798.	1/23/2018	14424959	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007176	Expedited	71	Female	USA	DE
799.	1/23/2018	14424960	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007184	Expedited	81	Male	USA	DE
800.	1/23/2018	14424961	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007221	Expedited	77	Male	USA	DE
801.	1/24/2018	14432258	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007216	Expedited	70	Male	USA	DE
802.	1/24/2018	14436569	1		Direct	78.2	Female	USA	DE
803.	1/25/2018	14443906	1		Direct	92	Female	USA	DE
804.	1/29/2018	14450328	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006664	Expedited	88	Male	USA	DE,HO
805.	1/29/2018	14453618	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006408	Expedited	77	Male	USA	DE
806.	1/29/2018	14453626	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007240	Expedited	76	Male	USA	DE
807.	1/29/2018	14453628	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007229	Expedited	79	Female	USA	DE
808.	1/29/2018	14453629	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006344	Expedited	75	Female	USA	DE
809.	1/31/2018	14465515	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003078	Expedited	84	Male	USA	DE,HO
810.	2/1/2018	14472425	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006543	Expedited	92	Female	USA	DE
811.	2/1/2018	14472566	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007298	Expedited	88	Male	USA	DE
812.	2/1/2018	14472594	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007310	Expedited	89	Male	USA	DE
813.	2/1/2018	14472620	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007319	Expedited	82	Female	USA	DE
814.	2/1/2018	14472648	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007311	Expedited	83	Male	USA	DE,HO
815.	2/2/2018	14478437	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007343	Expedited	74	Male	USA	DE
816.	2/2/2018	14478631	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007357	Expedited	76	Male	USA	DE
817.	2/2/2018	14478721	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007360	Expedited	71	Male	USA	DE
818.	2/2/2018	14478741	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007379	Expedited	78	Male	USA	DE
819.	2/2/2018	14484818	1		Direct	87	Female	USA	DE
820.	2/5/2018	14484056	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007361	Expedited	93	Female	USA	DE
821.	2/5/2018	14491804	1		Direct	83	Male	USA	DE
822.	2/6/2018	14490096	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006895	Expedited	71	Female	USA	DE
823.	2/6/2018	14490575	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007398	Expedited	69	Male	USA	DE
824.	2/6/2018	14490640	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007402	Expedited	80	Male	USA	DE
825.	2/6/2018	14490812	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007412	Expedited	91	Male	USA	DE
826.	2/7/2018	14495939	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007389	Expedited	90	Male	USA	DE
827.	2/7/2018	14495954	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007436	Expedited	88	Female	USA	DE
828.	2/7/2018	14495968	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007385	Expedited	NR	Male	USA	DE
829.	2/8/2018	14502091	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006295	Expedited	74	Female	USA	DE
830.	2/8/2018	14502321	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007444	Expedited	51	Female	USA	DE
831.	2/9/2018	14508617	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007448	Expedited	84	Female	USA	DE
832.	2/9/2018	14508639	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007451	Expedited	89	Female	USA	DE
833.	2/12/2018	14516781	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007488	Expedited	93	Female	USA	DE,HO
834.	2/12/2018	14517011	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007495	Expedited	77	Male	USA	DE
835.	2/13/2018	14523947	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007505	Expedited	74	Male	USA	DE

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	Initial FDA received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
836.	2/14/2018	14528409	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007517	Expedited	72	Male	USA	DE,HO
837.	2/14/2018	14528498	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007529	Expedited	78	Male	USA	DE
838.	2/14/2018	14528554	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007536	Expedited	85	Female	USA	DE
839.	2/14/2018	14528694	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007543	Expedited	88	Male	USA	DE
840.	2/14/2018	14528701	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007550	Expedited	85	Female	USA	DE
841.	2/15/2018	14532986	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007545	Expedited	84	Male	USA	DE
842.	2/15/2018	14533086	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007561	Expedited	80	Male	USA	DE
843.	2/16/2018	14538213	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007595	Expedited	88	Male	USA	DE
844.	2/16/2018	14538241	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007606	Expedited	87	Female	USA	DE
845.	2/19/2018	14546138	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007552	Expedited	72	Male	USA	DE
846.	2/19/2018	14546244	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007602	Expedited	79	Male	USA	DE
847.	2/19/2018	14546329	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007619	Expedited	87	Male	USA	DE
848.	2/19/2018	14550341	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006255	Expedited	73	Female	USA	DE
849.	2/20/2018	14550787	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-006973	Expedited	73	Male	USA	DE,HO
850.	2/20/2018	14550867	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007627	Expedited	68	Male	USA	DE
851.	2/20/2018	14550879	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007631	Expedited	75	Female	USA	DE
852.	2/20/2018	14551048	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007642	Expedited	81	Male	USA	DE
853.	2/21/2018	14556074	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007641	Expedited	69	Male	USA	DE
854.	2/21/2018	14556210	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007654	Expedited	73	Male	USA	DE
855.	2/21/2018	14556394	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007668	Expedited	72	Male	USA	DE
856.	2/21/2018	14556463	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007683	Expedited	77	Male	USA	DE
857.	2/22/2018	14560761	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007591	Expedited	83	Male	USA	DE
858.	2/22/2018	14560865	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007685	Expedited	83	Female	USA	DE
859.	2/22/2018	14560886	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007689	Expedited	85	Male	USA	DE
860.	2/22/2018	14560921	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007700	Expedited	81	Male	USA	DE
861.	2/23/2018	14565072	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007705	Expedited	82	Male	USA	DE
862.	2/26/2018	14570352	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007722	Expedited	78	Male	USA	DE
863.	2/26/2018	14570910	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007712	Expedited	77	Female	USA	DE
864.	2/26/2018	14571090	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007725	Expedited	82	Male	USA	DE
865.	2/26/2018	14571062	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007714	Expedited	82	Male	USA	DE
866.	2/28/2018	14580247	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007761	Expedited	NR	Female	USA	DE
867.	3/1/2018	14585095	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007759	Expedited	76	Female	USA	DE
868.	3/1/2018	14585149	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007770	Expedited	73	Male	USA	DE
869.	12/7/2016	13005891	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001443	Expedited	81	Male	USA	DE,HO,OT
870.	2/9/2017	13203062	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002162	Expedited	77	Male	USA	DE,OT
871.	3/23/2017	13363084	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002429	Expedited	81	Male	USA	DE,OT
872.	4/21/2017	13465644	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002944	Expedited	79	Male	USA	DE,HO,OT
873.	5/1/2017	13498061	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003157	Expedited	83	Male	USA	DE
874.	6/12/2017	13641072	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003717	Expedited	77	Male	USA	DE,OT
875.	6/14/2017	13649987	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003777	Expedited	86	Female	USA	DE,HO

FAERS Line Listing of Fatal Case Series for Pimavanserin, Received by FDA through March 4, 2018 (N=893)									
	Initial FDA received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
876.	7/4/2017	13713436	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004132	Expedited	79	Female	USA	DE,HO,OT
877.	7/26/2017	13795837	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004733	Expedited	79	Male	USA	DE
878.	7/31/2017	13814966	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004669	Expedited	82	Female	USA	DE
879.	8/14/2017	13868117	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004912	Expedited	85	Male	USA	DE,OT
880.	8/14/2017	13868124	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004930	Expedited	76	Female	USA	DE
881.	9/15/2017	13977706	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005492	Expedited	88	Female	USA	DE,HO,OT
882.	10/30/2017	14142156	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005974	Expedited	83	Female	USA	DE
883.	11/14/2017	14186319	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006130	Expedited	72	Female	USA	DE,HO
884.	11/17/2017	14200159	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006191	Expedited	77	Male	USA	DE
885.	11/30/2017	14239437	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006403	Expedited	74	Female	USA	DE,HO
886.	1/15/2018	14385088	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007025	Expedited	80	Male	USA	DE
887.	2/14/2018	14528517	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007534	Expedited	89	Male	USA	DE
888.	1/20/2017	13134387	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001885	Expedited	84	Male	USA	DE,HO
889.	8/2/2016	12615218	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000241	Expedited	89.3579	Female	USA	DE
890.	10/24/2016	12876533	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000997	Expedited	78.6173	Male	USA	DE
891.	11/15/2017	14194604	1		Direct	85.3	Male	USA	DE
892.	6/29/2016	12507321	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000024	Expedited	73.6317	Female	USA	DE
893.	1/22/2018	14425501	1		Direct	63	Female	USA	DE

*As per 21 CFR 314.80, the regulatory definition of serious is any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect, and other serious important medical events. This outcome should not be confused with the clinical outcome of the reported adverse drug experience. Those which are blank were not marked as serious (per the previous definition) by the reporter, and are coded as non-serious. A report may have more than one serious outcome.
Abbreviations: DE=Death, HO=Hospitalization, LT=Life-threatening, OT=Other medically significant

8.4. Appendix D. FAERS Line Listing of Torsade de Pointe/QT Prolongation Case Series

FAERS Line Listing of Torsade de Pointe/QT Prolongation Case Series for Pimavanserin, Received by FDA through March 4, 2018 (N=88)										
	Initial FDA Received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
1	6/29/2016	12507321	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000024	Expedited	73.63176	Female	USA	DE
2	7/29/2016	12605956	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000213	Expedited	77.66	Male	USA	OT
3	8/2/2016	12615218	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000241	Expedited	89.35797	Female	USA	DE
4	8/18/2016	12663743	5	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000194	Expedited	81.65	Female	USA	DE,HO,OT
5	8/31/2016	12703427	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000445	Expedited	73.87543	Female	USA	HO
6	8/31/2016	12703527	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000459	Expedited	61.95209	Male	USA	OT
7	9/5/2016	12714040	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000529	Expedited		Male	USA	OT
8	9/16/2016	12755952	1	US-ASTRAZENECA-2016SE80579	Non-Expedited		Male	USA	
9	10/12/2016	12838471	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000877	Expedited	74.52156	Male	USA	HO
10	10/24/2016	12876533	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000997	Expedited	78.61739	Male	USA	DE
11	11/14/2016	12938025	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000740	Non-Expedited	81.09514	Female	USA	
12	11/14/2016	12938564	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000434	Expedited		Female	USA	HO
13	11/14/2016	12938932	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000573	Non-Expedited		Male	USA	
14	12/7/2016	13005355	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001426	Expedited	54.14921	Female	USA	OT
15	12/7/2016	13005891	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001443	Expedited	80.88433	Male	USA	DE,HO,OT
16	12/14/2016	13026683	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001525	Expedited	83.01	Female	USA	HO
17	1/4/2017	13083316	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001723	Expedited		Male	USA	HO,LT,OT
18	1/20/2017	13134387	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001885	Expedited	83.8768	Male	USA	DE,HO
19	1/23/2017	13136975	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001738	Expedited		Male	USA	OT
20	2/9/2017	13203062	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002162	Expedited	77.42368	Male	USA	DE,OT
21	2/10/2017	13210682	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002186	Expedited	76.80767	Male	USA	HO,LT,OT
22	2/17/2017	13245830	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001893	Expedited	85.31964	Male	USA	HO,OT
23	2/20/2017	13252867	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001329	Non-Expedited		Male	USA	OT
24	2/20/2017	13253360	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001213	Non-Expedited	74.86927	Male	USA	OT
25	2/20/2017	13253394	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001832	Non-Expedited	84.69541	Female	USA	HO,OT
26	3/6/2017	13296746	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002387	Expedited	74	Male	USA	HO,OT
27	3/15/2017	13335597	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002471	Expedited	76.26831	Male	USA	HO,OT
28	3/23/2017	13363084	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002429	Expedited	81.11	Male	USA	DE,OT
29	3/27/2017	13375276	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002698	Expedited	71.24709	Male	USA	HO,OT
30	3/27/2017	13375278	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002689	Expedited	67.84	Female	USA	OT

FAERS Line Listing of Torsade de Pointe/QT Prolongation Case Series for Pimavanserin, Received by FDA through March 4, 2018 (N=88)									
	Initial FDA Received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
31	4/21/2017	13465644	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002944	Expedited	79.46	Male	USA	DE,HO,OT
32	5/1/2017	13498022	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003140	Expedited	82.03422	Male	USA	OT
33	5/1/2017	13498061	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003157	Expedited	82.94045	Male	USA	DE
34	5/4/2017	13512901	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003165	Expedited		Female	USA	OT
35	5/16/2017	13549568	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002468	Expedited	79.04	Female	USA	OT
36	5/17/2017	13556883	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002549	Non-Expedited	87.64956	Male	USA	
37	5/17/2017	13557525	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002742	Expedited	84.2601	Male	USA	HO,OT
38	5/17/2017	13557931	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002523	Expedited	74.00958	Male	USA	OT
39	6/12/2017	13641072	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003717	Expedited	77.27584	Male	USA	DE,OT
40	6/14/2017	13649987	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003777	Expedited	85.91	Female	USA	DE,HO
41	6/20/2017	13669362	1	US-EISAI MEDICAL RESEARCH-EC-2017-028457	Non-Expedited	79.01164	Female	USA	OT
42	7/4/2017	13713432	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004435	Expedited	81.41821	Male	USA	HO,OT
43	7/4/2017	13713436	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004132	Expedited		Null	USA	DE,HO,OT
44	7/10/2017	13739406	1	US-TEVA-785400USA	Expedited	84.15332	Female	USA	HO,OT
45	7/14/2017	13752785	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004573	Expedited	85.7358	Male	USA	OT
46	7/17/2017	13757890	5	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003565	Expedited	90.3436	Female	USA	HO
47	7/26/2017	13795837	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004733	Expedited	79.14579	Male	USA	DE
48	7/26/2017	13795845	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004741	Expedited	80.64066	Male	USA	OT
49	7/31/2017	13814966	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004669	Expedited	81.99589	Female	USA	DE
50	8/11/2017	13857674	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004970	Expedited	86.51061	Male	USA	HO,OT
51	8/14/2017	13866966	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003768	Non-Expedited	75	Female	USA	OT
52	8/14/2017	13866969	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003769	Non-Expedited	69	Male	USA	OT
53	8/14/2017	13867428	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004773	Expedited		Male	USA	HO,OT
54	8/14/2017	13867722	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003393	Non-Expedited		Male	USA	
55	8/14/2017	13868117	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004912	Expedited	84.94456	Male	USA	DE,OT
56	8/14/2017	13868124	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004930	Expedited		Null	USA	DE
57	8/29/2017	13915632	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005220	Expedited	78.13005	Female	USA	HO
58	9/6/2017	13941035	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005336	Expedited		Male	USA	HO
59	9/13/2017	13964413	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005214	Expedited	80.62	Male	USA	OT
60	9/13/2017	13964420	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005417	Expedited		Female	USA	HO,OT
61	9/15/2017	13977706	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005492	Expedited	88.48186	Female	USA	DE,HO,OT
62	10/3/2017	14032508	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005218	Expedited	92.01916	Male	USA	OT
63	10/6/2017	14054144	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005684	Expedited	84.00548	Female	USA	OT

FAERS Line Listing of Torsade de Pointe/QT Prolongation Case Series for Pimavanserin, Received by FDA through March 4, 2018 (N=88)									
	Initial FDA Received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
64	10/18/2017	14102534	1		Direct	63.92	Female	USA	HO
65	10/30/2017	14142156	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005974	Expedited	83.01437	Female	USA	DE
66	11/6/2017	14161434	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006054	Expedited	84.61328	Female	USA	OT
67	11/9/2017	14172192	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005794	Non-Expedited	67.93429	Female	USA	OT
68	11/9/2017	14173434	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005642	Non-Expedited	59.41958	Female	USA	OT
69	11/10/2017	14177581	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004974	Non-Expedited	83.05	Male	USA	OT
70	11/10/2017	14178151	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005373	Expedited	78.79535	Male	USA	HO
71	11/14/2017	14186319	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006130	Expedited		Null	USA	DE,HO
72	11/15/2017	14194604	1		Direct	85.3	Male	USA	DE
73	11/17/2017	14200159	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006191	Expedited		Null	USA	DE
74	11/22/2017	14212151	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006226	Expedited	90.86653	Male	USA	HO
75	11/27/2017	14225259	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006304	Expedited		Female	USA	OT
76	11/30/2017	14239437	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006403	Expedited	74.15469	Female	USA	DE,HO
77	12/8/2017	14263314	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006484	Expedited		Null	USA	OT
78	12/15/2017	14291177	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006657	Expedited		Null	USA	HO
79	12/22/2017	14318699	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006794	Expedited	74.74606	Male	USA	HO,OT
80	1/12/2018	14382031	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007042	Expedited		Null	USA	HO,OT
81	1/15/2018	14385088	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007025	Expedited		Null	USA	DE
82	1/22/2018	14425501	1		Direct	63	Female	USA	DE
83	2/9/2018	14508371	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007321	Expedited	64.33949	Female	USA	HO,OT
84	2/14/2018	14528517	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007534	Expedited		Male	USA	DE
85	2/16/2018	14538103	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007553	Expedited	79.68515	Male	USA	OT
86	2/19/2018	14546095	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007116	Expedited	81.70294	Female	USA	OT
87	2/19/2018	14550263	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006629	Non-Expedited		Female	USA	OT
88	2/21/2018	14556054	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007628	Expedited		Male	USA	HO,OT

*As per 21 CFR 314.80, the regulatory definition of serious is any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect, and other serious important medical events. This outcome should not be confused with the clinical outcome of the reported adverse drug experience. Those which are blank were not marked as serious (per the previous definition) by the reporter, and are coded as non-serious. A report may have more than one serious outcome.

Abbreviations: DE=Death, HO=Hospitalization, LT=Life-threatening, OT=Other medically significant

8.5. Appendix E. FAERS Line Listing of Other Events of Interest Case Series

FAERS Line Listing of Other Events of Interest Case Series for Pimavanserin, Received by FDA through March 4, 2018, Sorted by Adverse Event (N=61)									
	Initial FDA Received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
Seizure (N=27)									
1	8/18/2016	12663644	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000093	Expedited	70.48	Male	USA	HO
2	12/14/2016	13025415	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001531	Expedited	57.86721	Female	USA	OT
3	12/14/2016	13025422	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001512	Expedited	73.44	Male	USA	OT
4	12/29/2016	13070758	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001669	Expedited	79	Male	USA	HO,OT
5	12/30/2016	13074442	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001700	Expedited		Null	USA	HO,OT
6	1/12/2017	13107579	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001792	Expedited	66.33539	Male	USA	HO,OT
7	2/3/2017	13183533	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002128	Expedited	78.66667	Male	USA	OT
8	2/17/2017	13245494	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002231	Expedited	82	Male	USA	HO
9	3/1/2017	13280588	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002362	Expedited	77.99863	Female	USA	HO,OT
10	3/21/2017	13355275	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002627	Expedited	70.55989	Female	USA	HO
11	4/11/2017	13425378	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002906	Expedited	72.17796	Female	USA	HO,OT
12	5/2/2017	13502058	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003160	Expedited	76	Male	USA	OT
13	5/4/2017	13512922	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003199	Expedited	82.83915	Male	USA	OT
14	5/17/2017	13557751	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003147	Expedited	76.32	Male	USA	OT
15	5/17/2017	13557853	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002930	Expedited	87.65229	Female	USA	HO
16	6/14/2017	13649943	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003732	Expedited	61.72211	Male	USA	OT
17	6/14/2017	13649956	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003617	Expedited	66.99795	Male	USA	HO
18	7/14/2017	13752923	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004572	Expedited		Male	USA	OT
19	7/26/2017	13795821	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004714	Expedited	88.62	Female	USA	HO
20	8/16/2017	13871444	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005040	Expedited		Male	USA	HO,OT
21	8/23/2017	13896256	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005142	Expedited	85.15264	Male	USA	OT
22	9/6/2017	13940417	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005303	Expedited	90.59548	Female	USA	OT
23	9/22/2017	13999796	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005498	Expedited	80	Male	USA	HO,OT
24	9/27/2017	14015986	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005551	Expedited	72.81314	Male	USA	HO,OT
25	10/18/2017	14102134	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005815	Expedited	79	Female	USA	OT
26	10/27/2017	14135015	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005925	Expedited	76.27	Male	USA	HO,OT
27	12/22/2017	14318697	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006733	Expedited	83	Male	USA	OT
CVA (N=21)									
1	8/9/2016	12633936	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000284	Expedited	76.79	Female	USA	HO,LT
2	1/9/2017	13097152	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001756	Expedited	78.89391	Male	USA	HO
3	1/23/2017	13136992	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001922	Expedited	72.03285	Male	USA	HO,OT

FAERS Line Listing of Other Events of Interest Case Series for Pimavanserin, Received by FDA through March 4, 2018, Sorted by Adverse Event (N=61)									
	Initial FDA Received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*
4	3/27/2017	13375280	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002682	Expedited	77.81246	Female	USA	OT
5	4/14/2017	13442209	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002891	Expedited	80	Male	USA	HO
6	5/24/2017	13575536	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003513	Expedited	88.02464	Female	USA	HO
7	6/29/2017	13701062	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003788	Expedited	81.67	Female	USA	HO,OT
8	8/1/2017	13820255	1		Direct	81.62	Male	USA	HO
9	8/4/2017	13834141	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004857	Expedited	88	Female	USA	OT
10	8/14/2017	13867209	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004489	Expedited	81.48118	Male	USA	HO
11	8/14/2017	13867227	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004612	Expedited	89.60438	Female	USA	OT
12	8/14/2017	13867553	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004810	Expedited	77.12252	Male	USA	HO
13	9/6/2017	13941013	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005338	Expedited	63.76181	Female	USA	OT
14	9/22/2017	13999132	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005507	Expedited	63.9206	Female	USA	HO,OT
15	11/10/2017	14177927	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005239	Expedited	65.82615	Male	USA	HO,OT
16	12/5/2017	14253195	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006468	Expedited	88	Male	USA	OT
17	12/6/2017	14256285	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006470	Expedited	74.71321	Male	USA	HO,OT
18	2/19/2018	14550619	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006118	Expedited	74	Female	USA	OT
19	2/21/2018	14556344	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007657	Expedited	92	Female	USA	OT
20	2/27/2018	14576029	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007734	Expedited	93.42642	Male	USA	OT
21	3/1/2018	14585068	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007730	Expedited	88.12047	Male	USA	OT
MI (N=8)									
1	9/23/2016	12773811	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000682	Expedited	71.89049	Male	USA	HO
2	10/3/2016	12802573	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000809	Expedited	77	Male	USA	HO
3	10/6/2016	12817072	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000762	Expedited	77	Male	USA	HO
4	3/22/2017	13359170	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002657	Expedited	82	Female	USA	OT
5	4/11/2017	13425354	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002872	Expedited	68.28	Female	USA	HO,OT
6	7/11/2017	13743318	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003692	Expedited	73.95209	Male	USA	HO,OT
7	8/7/2017	13838112	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004876	Expedited	65.4757	Male	USA	HO
8	11/10/2017	14178035	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005269	Expedited	78	Null	USA	HO
VTE (N=11)									
1	8/16/2016	12653948	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000325	Expedited	70.01	Female	USA	HO,OT
2	10/13/2016	12843277	1	US-ASTRAZENECA-2016SF06573	Expedited		Female	USA	HO,OT
3	11/14/2016	12938084	8	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000840	Expedited	60.91	Male	USA	HO
4	3/30/2017	13386105	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002727	Expedited	64.37782	Male	USA	HO
5	9/11/2017	13955386	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005381	Expedited	77	Male	USA	HO
6	8/30/2017	13919337	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005226	Expedited	81.87269	Female	USA	HO
7	9/5/2017	13936145	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005329	Expedited	66.6694	Female	USA	HO

FAERS Line Listing of Other Events of Interest Case Series for Pimavanserin, Received by FDA through March 4, 2018, Sorted by Adverse Event (N=61)									
	Initial FDA Received Date	**FAERS Case #**	**Version #**	**Manufacturer Control #**	**Case Type**	**Age (years)**	**Sex**	**Country Derived**	**Serious Outcomes***
8	5/11/2017	13534936	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003342	Expedited	79.61	Male	USA	HO
9	9/26/2017	14011983	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005534	Expedited	74.73511	Male	USA	HO
10	1/8/2018	14363670	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-006958	Expedited	77	Female	USA	HO,OT
11	1/17/2018	14403849	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007126	Expedited	70.70226	Female	USA	HO,OT

*As per 21 CFR 314.80, the regulatory definition of serious is any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect, and other serious important medical events. This outcome should not be confused with the clinical outcome of the reported adverse drug experience. Those which are blank were not marked as serious (per the previous definition) by the reporter, and are coded as non-serious. A report may have more than one serious outcome.

Abbreviations: HO=Hospitalization, OT=Other medically significant

8.6. APPENDIX F. FAERS LINE LISTING OF OFF-LABEL USE CASE SERIES

FAERS Line Listing of PT *Off label use* Case Series for Pimavanserin, Received by FDA through March 4, 2018, Sorted by Reported Reason for Use (N=47)									
	Initial FDA Received Date	**FAERS Case #**	**Version #**	**Manufacturer Control #**	**Case Type**	**Age (years)**	**Sex**	**Country Derived**	**Serious Outcomes**[*†]
PD, NOS (N=12)									
1	12/14/2016	13025422	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001512	Expedited	73.44	Male	USA	OT
2	12/21/2016	13049779	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001589	Expedited	74.11636	Male	USA	OT
3	1/30/2017	13161730	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002027	Expedited	59.56	Male	USA	DE,HO,OT
4	1/30/2017	13162493	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002042	Expedited	NR	Male	USA	OT
5	2/14/2017	13229285	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002192	Expedited	49	Male	USA	HO
6	2/17/2017	13245830	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001893	Expedited	85.31964	Male	USA	HO,OT
7	4/20/2017	13460828	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003007	Expedited	77.60164	Female	USA	OT
8	7/12/2017	13745466	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004550	Expedited	56.9692	Male	USA	OT
9	8/4/2017	13834134	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004847	Expedited	84	Male	USA	DE
10	10/18/2017	14102534	1		Direct	63.92	Female	USA	HO
11	11/22/2017	14212154	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006266	Expedited	72.61054	Male	USA	DE,HO
12	12/5/2017	14253192	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006451	Expedited	79	Male	USA	DE
Non-PD (N=35)									
1	11/9/2016	12923694	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001144	Expedited	75	Male	USA	DE,HO
2	11/14/2016	12936611	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001189	Expedited	72.33949	Male	USA	DE
3	11/14/2016	12938402	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000299	Expedited	81	Male	USA	HO
4	11/18/2016	12955982	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001221	Expedited		Male	USA	DE
5	12/7/2016	13005355	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001426	Expedited	54.14921	Female	USA	OT
6	12/19/2016	13038554	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001545	Expedited	66	Female	USA	OT
7	12/23/2016	13057718	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001620	Expedited	64.59	Female	USA	HO
8	1/9/2017	13097389	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001790	Expedited	66.19	Male	USA	DE,OT
9	1/12/2017	13107597	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001804	Expedited	84.54757	Male	USA	DE
10	1/24/2017	13144838	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001986	Expedited	70.7269	Male	USA	HO,OT
11	2/20/2017	13253184	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001601	Expedited	65.36071	Male	USA	DE
12	2/24/2017	13268545	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002309	Expedited	78.04517	Female	USA	HO
13	2/27/2017	13273313	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002338	Expedited	83.44695	Male	USA	DE,HO,OT
14	3/17/2017	13345711	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002572	Expedited	73.34702	Male	USA	DE,OT
15	3/21/2017	13355293	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002667	Expedited	57	Male	USA	HO
16	3/27/2017	13375275	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002699	Expedited	79.04449	Female	USA	DE
17	3/27/2017	13375280	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002682	Expedited	77.81246	Female	USA	OT
18	4/24/2017	13470828	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003045	Expedited	86.94319	Female	USA	DE,HO
19	5/16/2017	13549416	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003327	Expedited	71.28816	Female	USA	DE

FAERS Line Listing of PT *Off label use* Case Series for Pimavanserin, Received by FDA through March 4, 2018, Sorted by Reported Reason for Use (N=47)									
	Initial FDA Received Date	**FAERS Case #**	**Version #**	**Manufacturer Control #**	**Case Type**	**Age (years)**	**Sex**	**Country Derived**	**Serious Outcomes*†**
20	5/16/2017	13549547	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003345	Expedited	87.68789	Male	USA	DE
21	5/17/2017	13557084	5	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002772	Expedited	73.07	Female	USA	HO
22	5/17/2017	13557710	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003100	Expedited	86.43669	Male	USA	HO,OT
23	6/12/2017	13644226	2	US-ABBVIE-17P-163-2003576-00	Expedited	86.43669	Male	USA	HO,OT
24	6/29/2017	13701063	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003582	Expedited	76	Male	USA	OT
25	7/3/2017	13709664	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004286	Expedited	77	Male	USA	DE
26	7/24/2017	13781027	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004694	Expedited	63	Male	USA	DE
27	8/14/2017	13867934	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004313	Expedited	79.03354	Female	USA	DE
28	10/3/2017	14032459	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005167	Expedited	95.15674	Female	USA	DE
29	10/10/2017	14068324	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005756	Expedited	70.92	Male	USA	HO
30	10/18/2017	14102143	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005832	Expedited	81	Female	USA	OT
31	11/27/2017	14225250	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006306	Expedited	76.40794	Male	USA	DE
32	12/21/2017	14313334	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006767	Expedited	53	Female	USA	HO
33	12/26/2017	14324981	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006802	Expedited	64	Female	USA	DE
34	2/1/2018	14472425	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006543	Expedited	92.47091	Female	USA	DE
35	2/19/2018	14546102	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006461	Non-Expedited	47.52361	Female	USA	OT

*As per 21 CFR 314.80, the regulatory definition of serious is any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect, and other serious important medical events. This outcome should not be confused with the clinical outcome of the reported adverse drug experience. Those which are blank were not marked as serious (per the previous definition) by the reporter, and are coded as non-serious. A report may have more than one serious outcome.
Abbreviations: DE=Death, HO=Hospitalization, DS= Disability, OT=Other medically significant
† Cases with a fatal outcome (i.e. DE) are also listed in the line listing table for the fatal case series.

8.7. Appendix G. FAERS Line Listing of Patients < 65 Years of Age Case Series

FAERS Line Listing of Patients < 65 Years of Age Case Series for Pimavanserin, Received by FDA through March 4, 2018 (N=93)									
	Initial FDA Received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*†
1	8/2/2016	12615220	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000243	Expedited	62.11	Male	USA	HO
2	8/10/2016	12640727	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000289	Expedited	54.92	Male	USA	HO
3	8/12/2016	12647159	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000304	Expedited	63.01	Male	USA	OT
4	8/18/2016	12663751	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000165	Expedited	54.68036	Male	USA	DE
5	8/26/2016	12689691	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000424	Expedited	61.99863	Male	USA	OT
6	9/29/2016	12790828	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000732	Expedited	64.16427	Male	USA	OT
7	10/3/2016	12802572	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000791	Expedited	60.72005	Female	USA	DE
8	10/20/2016	12869640	1		Direct	31.7	Female	USA	OT
9	10/24/2016	12876524	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000986	Expedited	61.65	Male	USA	DE,HO
10	10/24/2016	12884448	1		Direct	62.83	Male	USA	DE
11	11/2/2016	12903827	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000789	Expedited	62.67	Female	USA	OT
12	11/4/2016	12912032	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001109	Expedited	57.10883	Male	USA	HO
13	11/8/2016	12919086	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001067	Expedited	62.88843	Male	USA	DE
14	11/14/2016	12938084	8	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000840	Expedited	60.91	Male	USA	HO
15	11/14/2016	12938552	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000422	Expedited	61.10335	Male	USA	DE
16	11/14/2016	12938910	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000533	Expedited	57.1	Male	USA	HO,OT
17	12/7/2016	13005355	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001426	Expedited	54.14921	Female	USA	OT
18	12/12/2016	13017924	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001480	Expedited	64.6872	Male	USA	DS,OT
19	12/14/2016	13025415	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001531	Expedited	57.86721	Female	USA	OT
20	12/23/2016	13057718	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001620	Expedited	64.59	Female	USA	HO
21	1/16/2017	13118080	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001840	Expedited	58.83368	Male	USA	DE
22	1/23/2017	13136976	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001882	Expedited	55	Female	USA	HO
23	1/30/2017	13161730	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002027	Expedited	59.56	Male	USA	DE,HO,OT
24	1/30/2017	13163156	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002036	Expedited	64.93087	Male	USA	DE,HO
25	2/1/2017	13174347	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001645	Expedited	62.70226	Female	USA	DE
26	2/20/2017	13253128	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001524	Expedited	64.72	Male	USA	DE
27	2/20/2017	13253192	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2016-001616	Expedited	58.10541	Female	USA	HO
28	2/20/2017	13253719	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-001962	Expedited	64.2245	Male	USA	DE
29	2/22/2017	13260265	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002256	Expedited	63.59206	Male	USA	DE
30	3/6/2017	13296768	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002420	Expedited	58.69131	Male	USA	DE
31	3/8/2017	13304282	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002481	Expedited	62.74606	Female	USA	HO,OT
32	3/17/2017	13346308	1		Direct	58	Male	USA	DE
33	3/21/2017	13355285	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002640	Expedited	64.38877	Male	USA	DE,HO
34	3/23/2017	13363070	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002661	Expedited	51.22793	Male	USA	HO
35	3/30/2017	13386105	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002727	Expedited	64.37782	Male	USA	HO
36	3/30/2017	13386127	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002746	Expedited	54.99521	Male	USA	OT
37	4/6/2017	13407778	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002807	Expedited	63.15127	Male	USA	HO

FAERS Line Listing of Patients < 65 Years of Age Case Series for Pimavanserin, Received by FDA through March 4, 2018 (N=93)									
	Initial FDA Received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*†
38	4/18/2017	13452930	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002943	Expedited	62.37372	Male	USA	DE
39	4/18/2017	13452934	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002933	Expedited	64.52841	Male	USA	OT
40	4/26/2017	13482604	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003123	Expedited	59.35387	Male	USA	HO
41	4/28/2017	13495497	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003128	Expedited	61.71116	Female	USA	HO
42	5/5/2017	13517117	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003248	Expedited	61.98768	Male	USA	DE
43	5/8/2017	13522310	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003270	Expedited	64	Female	USA	DE
44	5/17/2017	13557695	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003087	Non-Expedited	56.36687	Male	USA	HO
45	5/17/2017	13557718	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-002983	Expedited	62.81	Male	USA	OT
46	5/17/2017	13557780	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003125	Non-Expedited	58.94045	Male	USA	HO
47	5/19/2017	13563792	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003431	Expedited	61.65092	Female	USA	HO
48	5/19/2017	13565419	4	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003510	Expedited	21.47296	Male	USA	HO
49	5/22/2017	13566706	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003456	Expedited	62.36824	Male	USA	HO
50	5/23/2017	13571023	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003480	Expedited	63.70979	Female	USA	HO
51	5/24/2017	13575554	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003524	Expedited	60.72827	Male	USA	HO
52	6/1/2017	13602926	1	US-TEVA-773697USA	Expedited	63.72621	Female	USA	OT
53	6/14/2017	13649943	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003732	Expedited	61.72211	Male	USA	OT
54	6/23/2017	13680782	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004113	Expedited	60	Male	USA	DE
55	7/3/2017	13709654	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004389	Expedited	53	Male	USA	HO
56	7/5/2017	13715848	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004427	Expedited	59.64408	Female	USA	HO
57	7/7/2017	13727303	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004479	Expedited	60.55031	Female	USA	HO
58	7/12/2017	13745466	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004550	Expedited	56.9692	Male	USA	OT
59	7/24/2017	13781027	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004694	Expedited	63	Male	USA	DE
60	7/26/2017	13795819	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004747	Expedited	59.32101	Male	USA	HO
61	7/28/2017	13802430	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004755	Expedited	49.67556	Male	USA	HO
62	8/14/2017	13867839	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-003720	Expedited	61.64	Female	USA	HO
63	8/18/2017	13880412	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005087	Expedited	46.74059	Male	USA	DE,HO
64	8/23/2017	13896234	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005107	Expedited	60.83778	Male	USA	OT
65	8/28/2017	13909312	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005143	Expedited	61.58522	Male	USA	HO,OT
66	8/29/2017	13915634	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005191	Expedited	64.90623	Male	USA	HO
67	8/30/2017	13919357	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005244	Expedited	61.13621	Male	USA	HO
68	9/6/2017	13941013	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005338	Expedited	63.76181	Female	USA	OT
69	9/20/2017	13992928	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005484	Expedited	63.04723	Female	USA	DE,OT
70	9/22/2017	13999132	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005507	Expedited	63.9206	Female	USA	HO,OT
71	10/18/2017	14102534	1		Direct	63.92	Female	USA	HO
72	10/23/2017	14114273	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005196	Expedited	63.56194	Male	USA	HO
73	10/25/2017	14123946	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005928	Expedited	63.55647	Female	USA	HO
74	10/27/2017	14135025	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005933	Expedited	62.92	Female	USA	HO
75	11/9/2017	14172181	5	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005882	Expedited	61.82	Male	USA	HO,OT

FAERS Line Listing of Patients < 65 Years of Age Case Series for Pimavanserin, Received by FDA through March 4, 2018 (N=93)									
	Initial FDA Received Date	FAERS Case #	Version #	Manufacturer Control #	Case Type	Age (years)	Sex	Country Derived	Serious Outcomes*†
76	11/9/2017	14172611	3	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005096	Expedited	60.75017	Male	USA	HO
77	11/9/2017	14172621	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005076	Expedited	64.03833	Female	USA	DE
78	11/9/2017	14173434	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-005642	Non-Expedited	59.41958	Female	USA	OT
79	11/9/2017	14174512	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006086	Expedited	63.05818	Male	USA	HO
80	11/9/2017	14174539	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006089	Expedited	39.7399	Male	USA	HO
81	11/10/2017	14177552	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-004959	Expedited	64.53	Female	USA	DE
82	11/10/2017	14179437	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006028	Expedited	60.74196	Male	USA	HO,OT
83	11/30/2017	14240469	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006398	Expedited	55.81109	Male	USA	HO
84	1/22/2018	14425501	1		Direct	63	Female	USA	DE
85	1/24/2018	14432253	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007198	Expedited	52.25188	Female	USA	OT
86	1/29/2018	14450388	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007203	Expedited	61.7358	Male	USA	HO
87	1/30/2018	14456084	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007277	Expedited	50.68036	Male	USA	HO
88	1/30/2018	14456142	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007284	Expedited	59.4935	Male	USA	HO
89	2/8/2018	14502321	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007444	Expedited	51.36208	Female	USA	DE
90	2/9/2018	14508371	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007321	Expedited	64.33949	Female	USA	HO,OT
91	2/12/2018	14516578	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007209	Expedited	56.36413	Female	USA	HO
92	2/19/2018	14546102	2	US-ACADIA PHARMACEUTICALS INC.-ACA-2017-006461	Non-Expedited	47.52361	Female	USA	OT
93	2/28/2018	14579962	1	US-ACADIA PHARMACEUTICALS INC.-ACA-2018-007416	Expedited	58.78439	Male	USA	OT

*As per 21 CFR 314.80, the regulatory definition of serious is any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect, and other serious important medical events. This outcome should not be confused with the clinical outcome of the reported adverse drug experience. Those which are blank were not marked as serious (per the previous definition) by the reporter, and are coded as non-serious. A report may have more than one serious outcome.
Abbreviations: DE=Death, HO=Hospitalization, DS= Disability, OT=Other medically significant
† Cases with a fatal outcome (i.e. DE) are also listed in the line listing table for the fatal case series.

8.8. APPENDIX H. DRUG UTILIZATION TABLE

Table 8.8.1. Total Number of Unique Patients Who Received a Dispensed Prescription For Nuplazid In The U.S., Stratified By Age Groups And Pharmacy Setting Of Care In The U.S., From April 2016 Through March 2018, Quarterly.

	Apr 2016-Jun		July 2016-Sept		Oct 2016-Dec		Jan 2017-Mar		Apr 2017-Jun		July 2017-Sept		Oct 2017-Dec		Jan 2018-Mar	
	Patient (N)	Share (%)	Patient (N)	Share (%)	Patient (N)	Share (%)	Patient (N)	Share (%)	Patient (N)	Share (%)	Patient (N)	Share (%)	Patient (N)	Share (%)	Patient (N)	Share (%)
Total NUPLAZID	(b) (4)	100.0%	(b) (4)	100.0%	(b) (4)	100.0%	(b) (4)	100.0%	(b) (4)	100.0%	(b) (4)	100.0%	(b) (4)	100.0%	(b) (4)	100.0%
0-9 years		(b) (4)		(b) (4)		(b) (4)		(b) (4) %		(b) (4)		(b) (4)		(b) (4)		(b) (4) %
10-19 years								%								%
20-39 years								%								%
40-59 years								%								%
60-69 years				%		%		%		%		%		%		%
70-79 years				%		%		%		%		%		%		%
80+ years				%		%		%		%		%		%		%
18-45 years*								%								%
46-65 years*								%								%
66-88 years*								%								%
89+ years*								%								%
Unknown Age		%		%				%								%
Total NUPLAZID		100.0%		100.0%		100.0%		100.0%		100.0%		100.0%		100.0%		100.0%
Mail-order/specialty		(b) (4) %		(b) (4)		(b) (4) %		(b) (4) %		(b) (4)		(b) (4) %		(b) (4) %		(b) (4)
ACADIA HUB		%				%		%				%		%		
Long-term care	Not Available															
Outpatient-retail	Not Applicable															

* Patient year of birth was not available for the unique patients listed under these age groupings.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

SARAH E KANG
07/05/2018

OFIR N NEVO
07/05/2018

ROBERT L LEVIN
07/05/2018

DANIEL S BAK
07/05/2018

ANDREW D MOSHOLDER
07/06/2018

TRAVIS W READY
07/06/2018

KIRA N LEISHEAR
07/06/2018

VICKY C CHAN
07/06/2018

GRACE CHAI
07/07/2018

SUKHMINDER K SANDHU
07/07/2018

CINDY M KORTEPETER
07/08/2018